॥ सा विद्या या विमुक्तये ॥

स्वामी रामानंद तीर्थ मराठवाडा विद्यापीठ, नांदेड

'ज्ञानतीर्थ', विष्णुपुरी, नांदेड – ४३१ ६०६ (महाराष्ट्र राज्य) भारत

SWAMI RAMANAND TEERTH MARATHWADA UNIVERSITY, NANDED

'Dnyanteerth', Vishnupuri, Nanded - 431 606 (Maharashtra State) INDIA

Established on 17th September, 1994, Recognized By the UGC U/s 2(f) and 12(B), NAAC Re-accredited with'B++' grade

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विज्ञान व तंत्रज्ञान विद्याशाखे अंतर्गत संलग्नित महाविद्यालयातील राष्ट्रीय शैक्षणिक धोरणानुसार पदव्युत्तर प्रथम वर्षाचे अभ्यासक्रम शैक्षणिक वर्ष २०२३–२४ पासून लागू करण्याबाबत.

प रि प त्र क

या परिपत्रकान्वये सर्व संबंधितांना कळविण्यात येते की, विज्ञान व तंत्रज्ञान विद्याशाखे अंतर्गत संलग्नित महाविद्यालयातील राष्ट्रीय शैक्षणिक धोरणानुसार पदव्युत्तर प्रथम वर्षाचे खालील अभ्यासक्रम शैक्षणिक वर्ष २०२३–२४ पासून लागू करण्याच्या दृष्टीन मा. कुलगुरू महोदयांनी विद्यापरिषदेच्या मान्यतेच्या अधीन राहून मान्यता दिलेली आहे.

1. M. Sc. Bioinformatics I year (Affiliated College)
2. M. Sc. Clinical Research I year (Affiliated College)

सदरील परिपत्रक व अभ्यासक्रम प्रस्तुत विद्यापीठाच्या **www.srtmun.ac.in** या संकेतस्थळावर उपलब्ध आहेत. तरी सदरील बाब ही सर्व संबंधितांच्या निदर्शनास आणून द्यावी, ही विनंती.

'ज्ञानतीर्थ' परिसर,
विष्णुपुरी, नांदेड – ४३१ ६०६.
जा.क्र.:शैक्षणिक–१/परिपत्रक/एनईपीपीजी/
२०२३–२४/251
दिनांक : २५.०८.२०२३.

आपली विश्वासू
सहा.कुलसचिव
शैक्षणिक (१–अभ्यासमंडळ) विभाग

प्रत माहिती व पुढील कार्यवाहीस्तव :

१) मा. अधिष्ठाता, विज्ञान व तंत्रज्ञान विद्याशाखा, प्रस्तुत विद्यापीठ.
२) मा. संचालक, परीक्षा व मूल्यमापन मंडळ यांचे कार्यालय, प्रस्तुत विद्यापीठ.
३) मा. प्राचार्य, सर्व संबधित महाविद्यालये, प्रस्तुत विद्यापीठ.
७) सिस्टम एक्सपर्ट, शैक्षणिक विभाग, प्रस्तुत विद्यापीठ. यानां देवून कळविण्यात येते की, सदरील परिपत्रक विद्यापीठाच्या संकेतस्थळावर प्रसिध्द करण्यात यावे.

SWAMI RAMANAND TEERTH

MARATHWADA UNIVERSITY, NANDED - 431 606

STRUCTURE AND SYLLABUS OF TWO YEAR MASTERS PROGRAM IN SCIENCE

SUBJECT: CLINICAL RESEARCH

Under the Faculty of

Science and Technology

M. Sc. First Year

(As per NEP-2020)

AFFILIATED COLLEGES

Effective From Academic Year 2023-2024

From the Desk of the Dean, Faculty of Science and Technology

Swami Ramanand Teerth Marathwada University, Nanded, enduring to its vision statement *"Enlightened Student: A Source of Immense Power",* is trying hard consistently to enrich the quality of science education in its jurisdiction by implementing several quality initiatives. Revision and updating curriculum to meet the standard of the courses at national and international level, implementing innovative methods of teaching-learning, improvisation in the examination and evaluation processes are some of the important measures that enabled the University to achieve the 3Es, the equity, the efficiency and the excellence in higher education of this region. To overcome the difficulty of comparing the performances of the graduating students and also to provide mobility to them to join other institutions the University has adopted the cumulative grade point average (CGPA) system in the year 2014-2015. Further, following the suggestions by the UGC and looking at the better employability, entrepreneurship possibilities and to enhance the latent skills of the stakeholders the University has adopted the Choice Based Credit System (CBCS) in the year 2018-2019 at graduate and post-graduate level. This provided flexibility to the students to choose courses of their own interests. To encourage the students to opt the world-class courses offered on the online platforms like, NPTEL, SWAYM, and other MOOCS platforms the University has implemented the credit transfer policy approved by its Academic Council and also has made a provision of reimbursing registration fees of the successful students completing such courses. SRTM University has been producing a good number of high caliber graduates; however, it is necessary to ensure that our aspiring students are able to pursue the right education. Like the engineering students, the youngsters pursuing science education need to be equipped and trained as per the requirements of the R&D institutes and industries. This would become possible only when the students undergo studies with an updated and evolving curriculum to match global scenario. Higher education is a dynamic process and in the present era the stakeholders need to be educated and trained in view of the self-employment and self-sustaining skills like start-ups. Revision of the curriculum alone is not the measure for bringing reforms in the higher education, but invite several other initiatives. Establishing industry-institute linkages and initiating internship, on job training for the graduates in reputed industries are some of the important steps that the University would like to take in the coming time. As a result, revision of the curriculum was the need of the hour and such an opportunity was provided by the New Education Policy 2020. National Education Policy 2020 (NEP 2020) aims at equipping students with knowledge, skills, values, leadership qualities and initiates them for lifelong learning. As a result the students will acquire expertise in specialized areas of interest, kindle their intellectual curiosity and scientific

temper, and create imaginative individuals. The curriculum given in this document has been developed following the guidelines of NEP-2020 and is crucial as well as challenging due to the reason that it is a transition from general science based to the discipline-specific-based curriculum. All the recommendations of the Sukanu Samiti given in the NEP Curriculum Framework-2023 have been followed, keeping the disciplinary approach with rigor and depth, appropriate to the comprehension level of learners. All the Board of Studies (BoS) under the Faculty of Science and Technology of this university have put in their tremendous efforts in making this curriculum of international standard. They have taken care of maintaining logical sequencing of the subject matter with proper placement of concepts with their linkages for better understanding of the students.

We take this opportunity to congratulate the Chairman(s) and all the members of various Boards of Studies for their immense contributions in preparing the revised curriculum for the benefits of the stakeholders in line with the guidelines of the Government of Maharashtra regarding NEP-2020. We also acknowledge the suggestions and contributions of the academic and industry experts of various disciplines. We are sure that the adoption of the revised curriculum will be advantageous for the students to enhance their skills and employability. Introduction of the mandatory On Job Training, Internship program for science background students is praise worthy and certainly help the students to imbibe first-hand work experience, team work management. These initiatives will also help the students to inculcate the workmanship spirit and explore the possibilities of setting up of their own enterprises.

Dr. M. K. Patil, ***Dean,*** *Faculty of Science and Technology*

Preamble:

The National Education Policy 2020 (NEP 2020) is formulated to revamp education system and lay down road map for new India. This policy is framed based on the fundamental pillars of access, equity, quality, affordability, and accountability and seeks to transform India into a thriving knowledge society and a global knowledge superpower.

Some of the important features of National Education Policy are Increasing gross enrolment ratio in higher education, Holistic and multidisciplinary education with multiple entry/exit options, Establishment of academic bank of credit, Setting up of multidisciplinary education and research Universities and National Research Foundation, Expansion of open and distance learning to increase gross enrolment ratio, Internationalization of education, Motivated, energized and capable faculty, Online and digital education and Effective governance and leadership.

As per the National Education Policy, the Government of Maharashtra has proposed a model curriculum framework and an implementation plan for the State of Maharashtra. It is to suggest and facilitate the implementation of schemes and programs, which improve not only the level of academic excellence but also improve the academic and research environment in the state. The proposed curriculum framework endeavors to empower the students and help them in their pursuit for achieving overall excellence.

In view of NEP priority and in-keeping with its vision and mission, process of updating the curriculum is initiated and implemented in SRTM University at UG and PG level from the academic year 2023-2024.

Clinical Research plays a pivotal role in advancing medical knowledge, improving patient care, and shaping the future of healthcare. This preamble serves as an overview and introduction to the syllabus for a comprehensive clinical research course. The syllabus aims to provide students with a solid foundation in the principles, methodologies, and ethical considerations of clinical research. By achieving these goals, graduates of the M.Sc. Clinical Research program will be well-prepared to pursue successful careers in various sectors of the clinical research industry, including academia, pharmaceuticals, CROs, government agencies, and healthcare organizations. They will make significant contributions to the advancement of clinical research and evidence-based healthcare practices.

To ensure uniform curriculum and its quality at PG level, curriculum and syllabus of different Institutions and Universities is referred to serve as a base in updating the same. The comments or suggestions from all teachers, students and other stakeholders are welcome for upbringing this curriculum

Salient Features:

1. M.Sc. Clinical Research programs offer a comprehensive curriculum that covers various aspects of clinical research, including research methodologies, study design, data analysis, ethical considerations, regulatory compliance, and more. The curriculum is designed to provide students with a strong theoretical foundation and practical skills necessary for conducting high-quality clinical research studies.
2. Interdisciplinary Approach: Clinical research involves collaboration among professionals from diverse fields. M.Sc. Clinical Research programs often adopt an interdisciplinary approach, bringing together faculty and students from different backgrounds such as medicine, pharmacy, nursing, and biostatistics, This fosters a multidisciplinary learning environment, allowing students to gain insights from various perspectives and develop effective teamwork skills.
3. Practical Training and Research Projects: M.Sc. Clinical Research programs emphasize practical training and hands-on experience. Students may have opportunities to participate in research projects, clinical trials, or internships, enabling them to apply their knowledge in real-world settings. This practical exposure enhances their research skills, critical thinking abilities, and prepares them for the challenges of the clinical research field.
4. Ethical Considerations and Regulatory Compliance: M.Sc. Clinical Research programs emphasize the importance of ethical conduct and compliance with regulatory guidelines in clinical research. Students learn about ethical principles, human subjects protection, informed consent, and the ethical challenges faced in conducting research. They gain an understanding of regulatory frameworks and guidelines such as Good Clinical Practice (GCP) and the Institutional Review Board (IRB) process.
5. Faculty Expertise: M.Sc. Clinical Research programs are often led by experienced faculty members who are experts in their respective fields. These faculty members bring their research experience and industry insights into the classroom, providing valuable guidance and mentorship to students. Their expertise contributes to the quality of education and helps students develop a strong foundation in clinical research.
6. Research Facilities and Resources: M.Sc. Clinical Research programs provide students with access to state-of-the-art research facilities, laboratories, and resources necessary for conducting clinical research. Students can benefit from the latest technologies, software tools, and databases to analyze data and generate meaningful research outcomes.
7. Career Development Opportunities: M.Sc. Clinical Research programs often offer career development support to students. This may include workshops on scientific writing,

presentation skills, job placement assistance, and networking opportunities with industry professionals. These initiatives enhance students' employability and help them transition into successful careers in clinical research.

8. Continuous Learning and Professional Growth: Clinical research is a rapidly evolving field, and M.Sc. Clinical Research programs encourage students to engage in continuous learning and professional growth. They may provide opportunities for attending conferences, workshops, and seminars, as well as encourage students to contribute to scientific publications or present their research findings. These activities enable students to stay updated with the latest advancements and make valuable contributions to the field.

Program Educational Objectives:

The Objectives of this program are:

PEO1: To equip students with a comprehensive understanding of the principles and practices of clinical research.

PEO2: To develop critical thinking, problem-solving, and analytical skills required for conducting and interpreting clinical research studies.

PEO3: To foster ethical conduct and adherence to regulatory guidelines in clinical research.

PEO4: To enhance communication and teamwork skills necessary for collaborating with interdisciplinary research teams.

PEO5: To promote professional growth and continuous learning in the field of clinical research.

Program Outcomes:

The Outcomes of this program are:

By the end of the program, graduates should be able to:

PO1: Demonstrate in-depth knowledge of clinical research methodologies and regulatory requirements.

PO2: Design, plan, and conduct clinical research studies ethically and effectively.

PO3: Analyze and interpret research data using appropriate statistical methods.

PO4: Communicate research findings through oral presentations and written reports.

PO5: Collaborate with healthcare professionals and researchers to contribute to advancements in medical science.

Prerequisite:

Basic knowledge of medical terminology, statistics, and research methodologies is also desirable. Applicants seeking admission to this program must have a Bachelor's degree in a relevant field (e.g. Life Sciences, Medicine, Pharmacy and Nursing) from any recognized institution.

Dr Sunita D Lohare
Chairman, BOS in Biotechnology and Bioinformatics,
Swami Ramanand Teerth Marathwada University,
Nanded-431606**.**

Details of the Board of Studies Members in the subject of Biotechnology, Bioinformatics and Clinical Research under the Faculty of Science & Technology, S.R.T.M. University, Nanded.

Sr No	Name of the Member	Designation	Sr No	Name of the Member	Designation
1	Dr Sunita Dhundiraj Lohare Shri Havgiswami Mahavidyalaya, Udgir, Dist -Latur Mob 9284161504	Chairman	2	Dr Babasaheb S Surwase School of Life Sciences SRTM University, Nanded 431606. Mob 9075829767	Member
3	Dr Pratap V. Deshmukh Nagnath Arts, Commerce and Science College, Aundha Nagnath, Dist. Hingoli Mob 9637202024	Member	4	Dr Komal S. Gomare Dept of Biotechnology, Dayanand Science College, Latur Mob 9284238413	Member
5	Dr Vaibhav D. Deshpande General Manager, Quality Corporate Office, Wockhardt, Mumbai Mob 9100988260	Member		--	
	Invitee Members				
6	Dr Laxmikant Kamble School of Life Sciences, SRTM University, Nanded 431606. Mob: 8669695555	Member	7	Dr M M V Baig Dept of Biotechnology, Yeshwant Mahavidyalaya, Nanded. Mob 9422170641	Member
8	Dr Sanjog T. Thul Environmental Biotechnology and Genomics Division, National Environmental and Engineering Research Institute (CSIR-NEERI). Nagpur. Mob 9881877072	Member	9	Dr Prashant Thakare Department of Biotechnology, SGB Amravati University, Amravati. Mob: 9822222822	Member
10	Dr Shivraj Hariram Nile Department of Food Science and Agriculture, National Agri-Food Biotechnology Institute (NABI), Mohali, Punjab. Mob 9561740707	Member	11	Dr Arun Ingale School of Life Sciences, North Maharashtra University, Umavinagar, Jalgaon. Mob: 9822708707	Member
12	Dr. Dhananjay S. Gond Department of Life Science, Swami Vivekanand Mahavidyalaya, Udgir. Mob: 98232 30378	Member	13	--	--

Swami Ramanand Teerth Marathwada University, Nanded

Faculty of Science & Technology

Credit Framework and Structure of Two Year PG Program (NEP 2020)

Subject: M Sc Clinical Research (Affiliated Colleges) (R-2023)

Year & Level	Sem	Major Subject		RM	OJT / FP/CS (3-Cr)	Research Project	Practicals (1-Cr)	Credits	Total Credits
		(DSC- 4 Cr)	(DSE- 3 Cr)						
1	1	SCLRC-401 Fundamentals of Clinical Operations SCLRC-402 Clinical Data Management SCLRC-403 Biostatistics for Clinical Research	SCLRE-401 Clinical Research and Pharmacovigilance **OR** SCLRE-403 Ethics in Medical Science	SVECR 401 Research Methodology (3-Cr)	--		SCLRP-401 Lab Course in Fundamentals of Clinical Operations SCLRP-402 Lab Course in Clinical Data Management SCLRP-403 Lab Course in Biostatistics for Clinical Research SCLRE-402 Lab Course in Clinical Research and Pharmacovigilance **OR** SCLRE-404 Lab Course in Ethics in Medical Science	22	44
	2	SCLRC-451 Clinical Study Design and Protocol Development SCLRC-452 Good Clinical Practices Guidelines SCLRC-453 Clinical Pharmacology	SCLRE-451 Clinical Research Quality Assurance **OR** SCLRE-453 Clinical Research Writing and Publication	---	SCLRX-451 (O/F/C)	--	SCLRP-451 Lab Course in Clinical Study Design and Protocol Development SCLRP-452 Lab Course in Good Clinical Practices Guidelines SCLRP-453 Lab Course in Clinical Pharmacology SCLRE-452 Lab Course in Clinical Research Quality Assurance **OR** SCLRE-454 Lab Course in Clinical Research Writing and Publication	22	
Exit option: Exit Option with PG Diploma in Clinical Research (After 2024-25)									
2	3	SCLRC-501 Regulatory Affairs SCLRC-502 Drug Design and Discovery SCLRC-503 Pharmacogenomics	SCLRE-501 Clinical Trial Operations **OR** SCLRE-503 Special Regulatory Process	--	--	Research Project SCLRR-551 (4-Cr)	SCLRP-501 Lab Course in Regulatory Affairs and Drug Design and Discovery SCLRP-502 Lab Course in Pharmacogenomics SCLRE-502 Lab Course in Clinical Trial Operations **OR** SCLRE-504 Lab Course in Special Regulatory Process	22	44
	4	SCLRC-551 Project Management and Business Development SCLRC-552 Audit & Inspection	SCLRE-551 Epidemiological Principles in Clinical Research **OR** SCLRE-553 Advanced Medical Writing / Coding	SVECP-551 Publication Ethics (2-Cr)	--	Research Project SCLRR-552 (6-Cr)	SCLRP-551 Lab Course in Project Management and Business Development SCLRP-552 Lab Course in Audit & Inspection SCLRE-552 Lab Course in Epidemiological Principles in Clinical Research **OR** SCLRE-554 Lab Course in Advance d Medical Writing / Coding	22	
Total Credits		44	12	05	03	10	14	**88**	

DSE indicates Department Specific Elective Course. Clinical Research student, in a particular semester, can opt either of these courses **OR** a course offered by the program of other Departments. DSC- Department Specific Core, OJT- On Job Training, FP- Field Project, CS- Case Study, RM- Research Methodology, Cr- Credit, VEC- Value Education Course, R- Revision, Credits of four semesters = 88, Total Marks of all four Semesters = 2200

M. Sc. First Year Semester I (Level 6.0)
Teaching Scheme

Subject	Course Code	Course Name	Credits Assigned			Teaching Scheme	
			Theory	Practical	Total	Theory (Hrs/ week)	Practical (Hrs/ Week/ Batch)
Major (DSC)	SCLRC-401	Fundamentals of Clinical Operations	04	--	04	04	--
	SCLRC-402	Clinical Data Management	04	--	04	04	--
	SCLRC-403	Biostatistics for Clinical Research	04	--	04	04	--
Elective (DSE)	SCLRE-401 SCLRE-403	Clinical Research and Pharmacovigilance **OR** Ethics in Medical Science	03	--	03	03	--
Research Methodology	SVECR-401	Research Methodology	03	--	03	03	
DSC Practical	SCLRP-401	Lab Course in Fundamentals of Clinical Operations	--	01	01	--	02
	SCLRP-402	Lab Course in Clinical Data Management	--	01	01	--	02
	SCLRP-403	Lab Course in Biostatistics for Clinical Research	--	01	01	--	02
DSE Practical	SCLRE-402 SCLRE-404	Clinical Research and Pharmacovigilance **OR** Lab Course in Ethics in Medical Science	--	01	01	--	02
		Total Credits	**18**	**04**	**22**	**18**	**08**

M. Sc. First Year Semester I (Level 6.0)
Examination Scheme

[20% Continuous Assessment (***CA)*** and 80% End Semester Assessment (***ESA***)]

Subject	Course Code	Course Name	Theory				Practical		Total
			Continuous Assessment (CA)			ESA			
			Test I	Test II	Avg of (T1+T2)/2	Total	CA	ESA	
Major (DSC)	SCLRC-401	Fundamentals of Clinical Operations	20	20	20	80	--	--	100
	SCLRC-402	Clinical Data Management	20	20	20	80	--	--	100
	SCLRC-403	Biostatistics for Clinical Research	20	20	20	80	--	--	100
Elective (DSE)	SCLRE-401 SCLRE-403	Clinical Research and Pharmacovigilance **OR** Ethics in Medical Science	15	15	15	60	--	--	75
Research Methodology	SVECR-401	Research Methodology	15	15	15	60	--	--	75
DSE Practical	SCLRP-401	Lab Course in Fundamentals of Clinical Operations	--	--	--	--	05	20	25
	SCLRP-402	Lab Course in Clinical Data Management	--	--	--	--	05	20	25
	SCLRP-403	Lab Course in Biostatistics for Clinical Research	--	--	--	--	05	20	25
DSE Practical	SCLRE-402 SCLRE-404	Lab Course in Clinical Research and Pharmacovigilance **OR** Lab Course in Ethics in Medical Science	--	--	--	--	05	20	25

M. Sc. First Year Semester II (Level 6.0)
Teaching Scheme

Subject	Course Code	Course Name	Credits Assigned			Teaching Scheme	
			Theory	Practical	Total	Theory (Hrs/ Week)	Practical (Hrs/ Week/ Batch)
Major (DSC)	SCLRC-451	Clinical Study Design and Protocol Development	04	--	04	04	--
	SCLRC-452	Good Clinical Practices Guidelines	04	--	04	04	--
	SCLRC-453	Clinical Pharmacology	04	--	04	04	--
Elective (DSE)	SCLRE-451 **OR** SCLRE-453	Clinical Research Quality Assurance **OR** Clinical Research Writing and Publication	03	--	03	03	--
On Job Training / Field Project/ Case Study	SCLRX-451	On Job Training (O) / Field Project (F)/ Case Study (C))	--	03	03	--	03
DSC Practical	SCLRP-451	Lab course in Clinical Study Design and Protocol Development	--	01	01	--	02
	SCLRP-452	Lab course in Good Clinical Practices Guidelines	--	01	01	--	02
	SCLRP-453	Lab course in Clinical Pharmacology	--	01	01	--	02
DSE Practical	SCLRE-452 **OR** SCLRE-454	Lab course in Clinical Research Quality Assurance **OR** Lab course in Clinical Research Writing and Publication	--	01	01	--	02
		Total Credits	**15**	**07**	**22**	**15**	**11**

M. Sc. First Year Semester II (Level 6.0)
Examination Scheme

[20% Continuous Assessment (**CA**) and 80% End Semester Assessment (**ESA**)]

Subject	Course Code	Course Name	Theory				Practical		Total
			Continuous Assessment (CA)			ESA			
			Test I	Test II	Avg of (T1+T2)/2	Total	CA	ESA	
Major (DSC)	SCLRC-451	Clinical Study Design and Protocol Development	20	20	20	80	--	--	100
	SCLRC-452	Good Clinical Practices Guidelines	20	20	20	80	--	--	100
	SCLRC-453	Clinical Pharmacology	20	20	20	80	--	--	100
Elective (DSE)	SCLRE-451 SCLRE-453	Clinical Research Quality Assurance **OR** Clinical Research Writing and Publication	15	15	15	60	--	--	75
On Job Training/ FieldProject/ Case Study	SCLRX-451	On Job Training (O) / Field Project (F) / Case Study (C)	--	--	--	--	15	60	75
DSE Practical	SCLRP-451	Lab course in Clinical Study Design and Protocol Development	--	--	--	--	05	20	25
	SCLRP-452	Lab course in Good Clinical Practices Guidelines	--	--	--	--	05	20	25
	SCLRP-453	Lab course in Clinical Pharmacology	--	--	--	--	05	20	25
DSE Practical	SCLRE-452 SCLRE-454	Lab course in Clinical Research Quality Assurance **OR** Lab course in Clinical Research Writing and Publication	--	--	--	--	05	20	25

SCLRC-401 FUNDAMENTALS OF CLINICAL OPERATIONS

Teaching Scheme.

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-401	Fundamentals of Clinical Operations	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC-401	Fundamentals of Clinical Operations	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic understanding of clinical research principles and concepts.
2. Familiarity with clinical trial processes and phases.
3. Knowledge of relevant regulatory guidelines, such as Good Clinical Practice (GCP).
4. Proficiency in data management and basic data analysis techniques.
5. Understanding of research ethics and compliance requirements.
6. Strong communication and collaboration skills.

Course Objectives:

1. To understand the basics of Clinical Operations.
2. To know the Mechanism of Drug action.
3. To become aware of basic terminologies used in Medical Sciences.

Course Outcomes: After successful completion of this course, students should be able to:

1. The students will understand the basics of Clinical operations such as Clinical Trials.

2. The students will identify the characteristics and basic concepts of Medical Sciences such as Medical Terms, Drugs action on systems (e.g. Nervous System, GI System etc.)

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Clinical Pharmacology**	15
	1.1	Drugs: Acting on Nervous System, Drugs Acting on Respiratory System	
	1.2	Drugs Acting on Gastrointestinal System, Drugs Acting on Cardiovascular System	
	1.3	Drugs Acting on Kidney, Autacoids and Related Drugs, Hormones and Related Drugs	
	1.4	Drugs Affecting Blood and Blood Formation, Antimicrobial Drugs, Anticancer Drugs.	
2.0	**II**	**Medical terminologies and Clinical Trails**	15
	2.1	Medical Terminologies, List of Symbols/Abbreviations/Terminologies, Clinical Research Terminologies, Glossary of Clinical Trials Terms	
	2.2	Introduction to Clinical trials, Types of Clinical Trials, Randomized Clinical Trial	
	2.3	Non Experimental clinical trials, Superiority trials	
	2.4	Phases of Clinical Trials	
3.0	**III**	**Site selection, and Closeout.**	15
	3.1	Introduction to Site Selection Visit, Flow of Events Prior to SSV, Feasibility Study,	
	3.2.	SSV Checklist, On Site visit, Elements of Discussion during the SSV.	
	3.3	Documentation and Follow-up of Persistent Non-Compliance at site.	
	3.4	Site Close Out, Flow of Events Prior to Site Close Out Visit, On Site Close Out visit.	
4.0	**IV**	**Unit V: Site Initiation & Site Monitoring**	15

	4.1	Reporting. Site initiation Visit : Introduction, Trials, Initiating the Study, Site initiation process	
	4.2	Procedure Site Monitoring and Site Close Out:	
	4.3	Monitor, Responsibility of the Monitor, Aims of Monitoring, Monitoring Plan.	
	4.4	Preparation for Monitoring Visits, Monitoring activities, Documenting the Monitoring Visit.	
		Total	**60**

References:

1. Satoskar RS, Bhandarkar SD, Ainapure SS. Hypolipidemic drugs. Pharmacology and Pharmacotherapeutics, 18th ed. Popular Prakashan, Mumbai, India. (2003)
2. Tripathi KD, Essentials of Medical Pharmacology Sixth Edition, Jaypee Brothers Medical Publishers(P) LTD New Delhi.
3. Rang, H. P., M. Maureen Dale, J. M. Ritter, and P. K. Moore. "Pharmacology, Churchill Livingstone." New York. (2003).
4. B. G. Katzung, S. B. Masters, A. J. Trevor, Basic and clinical pharmacology, 12th edition, Tata Mc Graw-Hill. (2013).
5. David Machin, Simon Day, Sylvan Green ,Text Book of Clinical Trials, , John Wiley & sons Ltd. (2004).
6. Caroline S. Zeind., Michael G. Carvalho, Applied Therapeutics,The Clinical use of Drugs, 7th edition, The Point Lippincott Williams & Wilkins.
7. *Richard D. Howland Mary J. Mycek Richard A. Harvey Pamela C. Champe,* Lippincott's Illustrated Reviews- Pharmacology, 3rd edition, Lippincott Williams & Wilkins. (2005).
8. H. L. Sharma, K. K. Sharma, Principles of Pharmacology, 3rd edition, Paras medical publisher. 2007)

SCLRP-401 LAB COURSE IN FUNDAMENTALS OF CLINICAL OPERATIONS

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Maintenance of laboratory animals as per CPCSEA guidelines.
5. Common laboratory techniques. Blood withdrawal, serum and plasma separation, anesthetics and euthanasia used for animal studies.

6. Study of different routes of drugs administration in mice/rats.
7. SOP - Investigator Site Close-out Procedure.
8. Site Close-out Visit Report.
9. Trial Site Close-out Checklist.
10. Various steps of Clinical Study Startup.

SCLRC-402 CLINICAL DATA MANAGEMENT

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-402	Clinical Data Management	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC-402	Clinical Data Management	20	20	20	80	--	--	100

Course Prerequisite:

1. Background in Life Sciences or related fields.
2. Basic understanding of clinical research principles.
3. Familiarity with data handling and computer skills.

Course Objectives:

1. To understand the basic principles & applications of Clinical Data Management.
2. To learn the various computers based programs such as System Validation, Database design, etc.

Course Outcomes:

After successful completion of this course, learner will be able to

1. Students will understand various tools of Data Management.
2. Students will learn CRF design & Database design.
3. Students will know the various computer bases methods of Clinical Data Management.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Clinical Data Management**	15
	1.1	Introduction to CDM, Computer system validation (CSV), Clinical Data Management flow, Data Management team	
	1.2	Roles and responsibilities of key team members and sponsor	
	1.3	SOPs of data management, review and authorization	
	1.4	CRF design Procedure for CRF design, elements of CRF, data points to be captured in individual CRFs	
2.0	**II**	**Database design, build up and Electronic Data Interchange (EDI).**	15
	2.1	Introduction to data base design and build, data base design, data base validation	
	2.2	Clinical data entry process Data entry screen validation, data entry process, symbols, data entering	
	2.3	Introduction, Definition, and Concept of Electronic Data Interchange	
	2.4	Architecture for EDI, Advantages of using EDI, barriers to implementation, positives and negatives.	
3.0	**III**	**Lab data loading and Quality Management of clinical data**	15
	3.1	Lab data loading -Roles and responsibilities of lab loader technician, helpdesk, study coordinator	
	3.2.	loading lab data, electronic/lab file contents, typical problems, lab data findings.	
	3.3	Quality Assurance, SOPs for processing lab data, taking lab data seriously.	
	3.4	Quality Control process, data errors and quality measurement, responsibilities, operational QC, data management matrix	
4.0	**IV**	**Database lock and Data Transfer**	15
	4.1	Introduction to data base lock	
	4.2	Minimum standards, procedure, errors found after database	

		closure, freezing the data base and best practices.	
	4.3	Recommended Standard Operating Procedures	
	4.4	Introduction to data transfer, procedure, best practices	
		Total	**60**

References:

1. Susanne Prokscha, Practical Guide to Clinical Data Management. 3rd Edition. CRC Press, Taylor and Francis Group. (2012)**.**
2. Martha L.,Sylyia, Mary F.Tertaak ,Clinical Analysis and Data Management for the DNP. 2nd Edition. Springer Publishing. (2018)**.**
3. Florian Leiner, Petra Khaup- Gregori.,Medical Data Management: A Practical Guide (Health Informatics series),Springer. (2003).
4. Richard K. Rondel,Sheila A. Varley, Colin F.Webb, Clinical Data Management 2nd Edition., John Wiley and Sons Ltd. Chichester. (2002)

SCLRP-402 LAB COURSE IN CLINICAL DATA MANAGEMENT

1. Preparation of Data Management Plan including Minimum Standards, Creation, Maintenance & Organization.
2. Data Management standards in Clinical Research.
3. CRF Design with printing & vendor selection.
4. Database validation.
5. Laboratory data handling.
6. Tools used in Data Privacy.
7. Metrics in Clinical Data Management
8. Database Closure.

SCLRC-403 BIOSTATISTICS FOR CLINICAL RESEARCH

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-403	Biostatistics For Clinical Research	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC-403	Biostatistics For Clinical Research	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic knowledge of mathematics and statistics.
2. Familiarity with medical terminology and concepts**.**

Course Objectives:

1. The aim of this course is to develop core statistical skills for interpreting clinical and epidemiological data.
2. To enrich the understanding of biostatistician procedure in clinical research which sponsor, CRO and Hospital use in clinical trials.
3. To know the importance of biostatistics in clinical trials.

Course Outcomes:

After completion of this course students will be able to

1. Apply basic statistical concepts commonly used in public health and health Sciences.
2. Demonstrate basic analytical techniques to generate results.
3. Interpret results of commonly used statistical analyses in written summaries.

4. Demonstrate statistical reasoning skills accurately and contextually.
5. Apply statistical knowledge to design and conduct research studies.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Biostatistics**	15
	1.1	Basic Definitions and Applications in clinical research	
	1.2	Sampling - Representative sample, Sample size, Sampling bias, Sampling technique	
	1.3.	Data Collection and presentation - Types of data, Methods of collection of primary and secondary data, Methods of data presentation	
	1.4	Graphical representation - Histogram, Polygon, Ogive curves, Pie diagram.	
2.0	II	**Measures of Central Tendency**	15
	2.1	Measures of Central Tendency: Mean, Median and Mode	
	2.2	Measures of Dispersion/Variability- standard deviation, standard error, range, Variance, mean deviation	
	2.3	Correlation and Regression, Bivariate data and scatter diagram, Simple (linear) & correlation and regression, Multiple linear regression	
	2.4	Coefficient of correlation and regression and their properties, ANOVA: Definition and Classification.	
3.0	**III**	**Tests of significance and Designing of Experiment**	15
	3.1	The concept of Null and alternative hypothesis	
	3.2	Parametric and non-parametric tests of significance - Small Sample Test, Chi-Square test, t-test, F-test,	
	3.3	Large Sample Test (Z-test), Standard Error	

	3.4	Experimental designs-Completely Randomized Design, Randomized Block Design. Latin square design. Factorial designs.	
4.0	**IV**	**Introduction to Probability Theory**	15
	4.1	Definition, Elementary properties, Types, Rules of probability and Its applications to biological problems	
	4.2	Probability Distributions- Definitions, Probability distribution curves.	
	4.3	Continuous probability distribution-Normal distribution, properties and applications	
	4.4	Discrete probability distribution-Binomial &Poisson distribution, properties and applications.	
		Total	**60**

References:

1. Bliss, C.I.K. Statistics in Biology, Vol. 1. Mc Graw Hill, New York. (1967).
2. Wardlaw, A.C. Practical Statistics for Experimental Biologist. (2000)
3. Bailey, N.T. Statistical Methods in Biology. English Univ. Press. (2000).
4. Khan, Irfan A. Fundamentals of Biostatistics. Ukaaz Publications. (2004)
5. John M.L Biostatistical Methods. John Wiley & Sons. (2007)
6. Wayne W. Daniel, Biostatistics - 7th Edition. John Wiley & Sons.
7. Murthy, M.N. Sampling Methods. Indian Statistical Institute, Kolkata. (1967)
8. Arora and Malhan Biostatistics. Himalaya Publishing House. (2002)
9. Rosner Bernard, Fundamentals of Biostatistics (5th ed.). Ed. Duxbury Thomson. (2002).
10. Montgomery, D.C. Design and Analysis of Experiments. John Wiley & Sons.(2017)
11. Campbell, R.C. Statistics for Biologist. Cambridge University Press, UK (1974).

SCLRP-403 LAB COURSE IN BIOSTATISTICS FOR CLINICAL RESEARCH

1. Collection of data & statistical calculations
2. Representation of statistical data by
   - Histogram
   - Ogive curve

- Pie diagram

3. Problems based on measure of central tendency.
4. Problems based on measure of dispersion.
5. Problems based on test of significance-t-test, F-test, chi-square test.
6. Problems based on correlation & regression.
7. Problems based on Probability

SCLRE-401 CLINICAL RESEARCH AND PHARMACOVIGILANCE

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-401	Clinical Research and Pharmacovigilance	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE-401	Clinical Research and Pharmacovigilance	15	15	15	60	--	--	75

Course Prerequisite:

1. Medical or Life Sciences Background
2. Good Communication Skills
3. Knowledge of Research Methods
4. Ethical Awareness
5. Data Management Skills
6. Regulatory Understanding
7. Critical Thinking

Course Objectives:

1. To provide a value addition and current requirement for the students in clinical research and pharmacovigilance.
2. To focus on global scenario of Pharmacovigilance in different methods that can be used to generate safety data.

Course Outcomes:

After completion of this course students will be able to

1. Explain the regulatory requirements for conducting clinical trial
2. Demonstrate the types of clinical trial designs
3. Explain the responsibilities of key players involved in clinical trials
4. Execute safety monitoring, reporting and close-out activities
5. Explain the principles of Pharmacovigilance
6. Detect new adverse drug reactions and their assessment
7. Perform the adverse drug reaction reporting systems and communication in Pharmacovigilance.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Regulatory Perspectives of Clinical Trials**	12.
	1.1	Origin and Principles of International Conference on Harmonization - Good Clinical Practice (ICH-GCP) guidelines	
	1.2	Ethical Committee: Institutional Review Board, Ethical Guidelines for Biomedical Research and Human Participant- Schedule Y, ICMR	
	1.3.	Informed Consent Process: Structure and content of an Informed Consent Process	
	1.4	Ethical principles governing informed consent process	
2.0	**II**	**Clinical Trials and Documentation**	11.
	2.1	Types and Design Experimental Study- RCT and Non RCT, Observation Study: Cohort, Case Control, Cross sectional	
	2.2	Clinical Trial Study Team- Roles and responsibilities of Clinical Trial Personnel: Investigator, Study Coordinator, Sponsor, Contract Research Organization and its management	
	2.3	Guidelines to the preparation of documents, Preparation of protocol, Investigator Brochure, Case Report Forms, Clinical Study Report	

	2.4	Clinical Trial Monitoring- Safety Monitoring in CT Adverse Drug Reactions: Definition and types. Detection and reporting methods	
3.0	**III**	**Basic aspects, terminologies and establishment of pharmacovigilance**	11
	3.1	History and progress of pharmacovigilance, Significance of safety monitoring	
	3.2	Pharmacovigilance in India and international aspects, WHO international drug monitoring programme, WHO and Regulatory terminologies of ADR, evaluation of medication safety	
	3.3	Establishing pharmacovigilance centres in Hospitals, Industry and National programmes related to pharmacovigilance	
	3.4	Roles and responsibilities in Pharmacovigilance	
4.0	**IV**	**Methods, ADR reporting and tools used in Pharmacovigilance**	11
	4.1	International classification of diseases, International Nonproprietary names for drugs.	
	4.2	Passive and Active surveillance, Comparative observational studies, targeted clinical investigations and Vaccine safety surveillance.	
	4.3	Spontaneous reporting system and Reporting to regulatory authorities, Guidelines for ADRs reporting.	
	4.4	Argus, Aris G Pharmacovigilance, VigiFlow, Statistical methods for evaluating medication safety data.	
		Total	**45**

References:

1. Central Drugs Standard Control Organization- Good Clinical Practices, Guidelines for Clinical Trials on Pharmaceutical Products in India. New Delhi: Ministry of Health; (2001).
2. International Conference on Harmonization of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonized Tripartite Guideline. Guideline for Good Clinical Practice.E6; May (1996).
3. Ethical Guidelines for Biomedical Research on Human Subjects . Indian Council of Medical Research, New Delhi.(2000).
4. David Machin, Simon Day and Sylvan Green, Textbook of Clinical Trials, 2nd Edition, John

Wiley and Sons.,(2004).

5. Richard K. Rondel,Sheila A. Varley, Colin F.Webb, Clinical Data Management 2nd Edition., John Wiley and Sons Ltd. Chichester.(2002)
6. Julia Lloyd and Ann Raven, Handbook of clinical Research In the Pharmaceutical industry., 2nd Edition,Churchill Livingstone.(1994).
7. Ignazio Di Giovanna Gareth hayes, Principles of Clinical Research, Writeson Biomedical Publishing,(2001).

SCLRE-402 LAB COURSE IN CLINICAL RESEARCH AND PHARMACOVIGILANCE

1. Protocol design for clinical trial. (3 Nos.)
2. Design of ADR monitoring protocol.
3. In-silico docking studies. (2 Nos.)
4. In-silico Pharmacophore based screening.
5. In-silico QSAR studies.
6. ADR reporting

SCLRE-403 ETHICS IN MEDICAL SCIENCE

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-403	Ethics in Medical Science	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE -403	Ethics in Medical Science	15	15	15	60	--	--	75

Course Prerequisite:

1. Basic Understanding of Medical Concepts
2. Ethical Awareness and Sensitivity
3. Critical Thinking Skills
4. Knowledge of Research Principles
5. Respect for Patient Rights and Privacy
6. Openness to Discussions on Ethical Dilemmas
7. Commitment to Adhering to Ethical Guidelines.

Course Objectives:

1. To understand ethical principles in medical practice.
2. To develop awareness of ethical dilemmas in healthcare.
3. To apply ethical reasoning to medical decision-making.
4. To respect and protect patient rights and confidentiality.
5. To comply with ethical guidelines and codes of conduct.

6. To foster empathy and compassion in patient care.
7. To communicate effectively about ethical issues in medicine.
8. To cultivate a commitment to ethical behavior in medical practice.

Course Outcomes:

After successful completion of this course, students will have

1. Enhanced understanding of ethical principles in healthcare.
2. Increased ability to identify and address ethical dilemmas.
3. Improved ethical decision-making in medical practice.
4. Strengthened commitment to patient rights and privacy.
5. Adherence to ethical guidelines and professional conduct.
6. Heightened empathy and compassionate patient care.
7. Effective communication about ethical issues in medicine.
8. Development of a strong ethical foundation in medical practice.

Curriculum Details

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**UNIT I**	11
	1.1	Introduction: Evolution of ethics in clinical research	
	1.2	Tuskegee experiment, Nuremberg Code, Declaration of Helsinki, Belmont report	
	1.3	Establishment of CIOMS, NIH and ICMR guidelines, Legal Liability in Clinical research, negligence, strict liability, criminal liability.	
	1.4	Legal obligations of the investigator, Compensation to subjects/patients for clinical trial related injuries.	
2.0	**II**	**UNIT II**	11
	2.1	Objectives· what's special about medicine what's special about medical ethics.	
	2.2	Who decides what ethical Does medical ethics change?	
	2.3	Does medical ethics differ from one country to another the role of the WMA.	
	2.4	How does the WMA decide what is ethical How do individuals decide what is ethical. Conclusion.	
3.0	**III**	**UNIT III**	11
	3.1	Approaches to Ethical Analysis	
	3.2	.Feminist Approaches to Ethics, Principles.	

	3.3	Deontology, Utilitarianism	
	3.4	Contract-Based Ethics, Virtue Ethics, Pragmatism	
4.0	**IV**	**UNIT IV**	12
	4.1	Overview of IRB/IEC/ERB, Independent Ethics Committees	
	4.2	Ethics review procedure, Importance of Inform Consent Document; Patient Information Sheet & Inform Consent Form.	
	4.3	Fraud and misconduct, detection of fraud in clinical research Ethics in academia. Violations of ethics in research	
	4.4	Responsibilities and privileges of physicians, Responsibilities to oneself, the future of medical ethics	
		Total	**45**

References:

1. Gupta S.K, Basic Principles of Clinical Research and Methodology; Jaypee Brothers and Medical Publishers; First Edition. (2007).
2. Ezekiel J. Emanuel, Christine C. Grady, Robert A. Crouch,Oxford Text Book of Clinical Research Ethics, Oxford University Press. (2008).
3. Sana Loue, Textbook of Research Ethics Theory and Practice, Publisher, Springer US. (2013).
4. John R. Williams, World Medical Association Medical Ethics Manual 3rd edition, Cataloguing-in-Publication Data. (2015).

SCLRE-404 LAB COURSE IN ETHICS IN MEDICAL SCIENCE

1. The Nuremberg Code and Declaration of Helsinki
2. Legal Liability in Clinical research.
3. Feminine Approaches to Ethics.
4. Legal obligations of the investigator.
5. CIOMS, NIH and ICMR guidelines

SVECR-401 RESEARCH METHODOLOGY

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SVECR-401	Research Methodology	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SVECR -401	Research Methodology	15	15	15	60	--	--	75

Course Prerequisite:

1. The course requires prior knowledge, and a foundational understanding of the subject and are essential to contextualizing their research and formulating relevant research questions.
2. Basic knowledge and understanding of statistics, communicative English, and computer awareness are essential.

Course Objectives:

1. To familiarize the students with fundamental research concepts, such as hypothesis formulation, data collection, and data analysis.
2. To inculcate, understand, and apply principles of research methodology learning the necessary skills to conduct rigorous and effective research in their respective fields..

Course Outcomes:

After successful completion of this course, students should be able to:

1. Develop critical thinking abilities,
2. Learn various research methods
3. Acquire the tools required to design and execute research projects.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Research**	12
	1.1	Introduction and definition of research	
	1.2	General characteristic and functions of research	
	1.3.	Objectives and types of research	
	1.4	Scientific and reflective thinking	
2.0	**II**	**The Research Problem**	13
	2.1	Identification, source, and criteria for selection, characteristics of problem	
	2.2	Hypothesis: meaning. nature, function, formulation, and testing	
	2.3	Research proposal or synopsis	
	2.4	Literature review: objectives, principles, procedure, and sources	
3.0	**III**	**Collection and Analysis of Data**	10
	3.1	Data: methods of Collection and techniques	
	3.2	Qualitative and quantitative data analysis	
	3.3	Experimental data and regression analysis	
4.0	**IV**	**The Research Report**	10
	4.1	Format, Process, Style, Form	
	4.2	Contents of Research Paper, Reports, and Theses	
	4.3	Ethics in publication and plagiarism	
		Total	**45**

References:

1. Creswell, J. W., & Creswell, J. D. Research Design: Qualitative, Quantitative, and Mixed Methods Approaches. Sage Publications. 2017.
2. Kumar, R. Research Methodology: A Step-by-Step Guide for Beginners. SAGE Publications.
3. Booth, W. C., Colomb, G. G., & Williams, J. M. 2008. The Craft of Research. University of Chicago Press. 2021.
4. Comstock, G. Research Ethics: A Philosophical Guide to the Responsible Conduct of Research. Routledge. 2017.
5. Alley, M. The Craft of Scientific Writing. Springer. 2019.
6. American Psychological Association APA. Publication Manual of the American Psychological Association. American Psychological Association. 2020.
7. Laake, P., Benestad, H. B., & Olsen, B. R. Research Methodology in the Medical and Biological Sciences [1st ed.]. Academic Press. 2007.
8. Kothari, C. R. Research Methodology: Methods and Techniques. New Age International. 2004.
9. Bickel, R. Methodology In The Social Sciences Multilevel Analysis for Applied Research: It's Just Regression. Guilford Press. 2007.

SEMESTER- II

SCLRC-451 CLINICAL STUDY DESIGN AND PROTOCOL DEVELOPMENT

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-451	Clinical Study Design and Protocol Development	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC -451	Clinical Study Design and Protocol Development	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic knowledge of medical terminology and concepts.
2. Familiarity with research methodology and statistics.
3. Understanding of ethical principles in clinical research.

Course Objectives:

1. To understand the principles of clinical study design and its significance in medical research.
2. To develop a comprehensive clinical research protocol with clear objectives and outcomes.
3. To apply ethical considerations in study design, participant selection, and data handling.

4. To demonstrate the ability to calculate sample sizes and plan statistical analyses for research studies.

Course Outcomes:

After successful completion of this course, Students will be able to:

1. Analyze different study designs and select the most appropriate design for specific research questions.
2. Create a well-structured clinical research protocol addressing all essential components.
3. Identify and address ethical considerations in clinical study design and participant recruitment.
4. Calculate sample sizes and understand statistical concepts relevant to study planning.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Clinical Study Design**	15
	1.1	Overview of clinical research and its importance in healthcare.	
	1.2	Types of clinical research studies (observational, interventional, etc.).	
	1.3.	Factors to consider in selecting a research question and study design.	
	1.4	Identifying study objectives and outcomes.	
2.0	**II**	**Developing a Clinical Research Protocol**	15
	2.1	Components of a clinical research protocol.	
	2.2	Writing research questions and hypotheses.	
	2.3	Study population and inclusion/exclusion criteria.	
	2.4	Sample size calculation and statistical considerations.	
3.0	**III**	**Ethical Considerations in Study Design**	15
	3.1	Informed consent process and its significance.	
	3.2	Addressing ethical issues in vulnerable populations.	

	3.3	Balancing risks and benefits in study design	
	3.4	Ensuring patient safety and data confidentiality.	
4.0	**IV**	**Practical Aspects of Protocol Development**	15
	4.1	Data collection methods and tools.	
	4.2	Study timeline and budget planning.	
	4.3	Protocol amendments and protocol deviation handling.	
	4.4	Preparing for ethical review and regulatory approval.	
		Total	**60**

References:

1. Stephen B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah G. Grady, Thomas B. Newman. "Designing Clinical Research."
2. Robert H. Fletcher, Suzanne W. Fletcher, and Grant S. Fletcher. "Clinical Epidemiology: The Essentials."
3. John I. Gallin and Frederick P. Ognibene. "Principles and Practice of Clinical Research."

SCLRP- 451 LAB COURSE IN CLINICAL STUDY DESIGN AND PROTOCOL DEVELOPMENT

1. Developing a clinical research protocol and study objectives.
2. Calculating sample sizes for different study designs.
3. Handling ethical considerations in participant selection and informed consent.
4. Preparing a timeline and budget for a clinical research study.

SCLRC-452 GOOD CLINICAL PRACTICES GUIDELINES

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-452	Good Clinical Practices Guidelines	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC -452	Good Clinical Practices Guidelines	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic knowledge of clinical research concepts and terminology.
2. Familiarity with the ethical principles in medical research.
3. Understanding of clinical trial protocols and study design.

Learning Objectives:

1. To understand the importance of Good Clinical Practices (GCP) guidelines in ensuring ethical conduct and data integrity in clinical trials.
2. To familiarize with the essential elements and requirements of GCP in clinical research.
3. To develop the skills to implement GCP principles throughout the clinical trial process.
4. To prepare for GCP audits and regulatory inspections to ensure compliance.

Course Outcomes:

After successful completion of this course, students should be able to:

1. Explain the role of GCP guidelines in maintaining participant safety and data reliability.
2. Apply GCP principles in the informed consent process and documentation.
3. Identify and adhere to the responsibilities of investigators, sponsors, and IRBs in clinical trials.
4. Implement quality assurance measures to ensure GCP compliance in research.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Good Clinical Practices (GCP)**	15
	1.1	Overview of GCP guidelines and their significance in clinical research.	
	1.2	Historical development and evolution of GCP.	
	1.3.	International regulations and organizations governing GCP.	
	1.4	Principles of ethical conduct in clinical trials.	
2.0	**II**	**Essential Elements of GCP**	15
	2.1	Informed consent process and documentation.	
	2.2	Investigator responsibilities and qualifications.	
	2.3	Institutional Review Board (IRB) or Ethics Committee oversight.	
	2.4	Adverse event reporting and safety monitoring.	
3.0	**III**	**Implementing GCP in Clinical Trials**	15
	3.1	GCP in the design and conduct of clinical trials.	
	3.2	Data integrity and accurate documentation.	
	3.3	Quality assurance and quality control in clinical research.	
	3.4	Role of sponsors, monitors, and auditors in ensuring GCP compliance.	
4.0	**IV**	**Ensuring Compliance and Good Clinical Practice Audits**	
	4.1	Regulatory inspections and audits in clinical trials.	
	4.1	Addressing deficiencies and corrective actions.	

	4.2	Impact of non-compliance on trial validity and participant safety.	15
	4.3	Importance of continuous training and education in GCP.	
		Total	**60**

References:

1. Good Clinical Practice: A Question & Answer Reference Guide" by GCP (R) Journal.
2. ICH Guidelines for Good Clinical Practice E6 (R2)" by International Council for Harmonisation.
3. A Guide to Good Clinical Practice (GCP) for Clinical Trials in Europe" by European Medicines Agency.

SCLRP 452 LAB COURSE IN GOOD CLINICAL PRACTICES GUIDELINES

1. Role-playing exercises for conducting informed consent interviews.
2. Case studies on ethical dilemmas in clinical trials and GCP compliance.
3. Mock GCP audits to evaluate trial documentation and adherence to GCP guidelines

SCLRC-453 CLINICAL PHARMACOLOGY

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRC-453	Clinical Pharmacology	04	--	04	--	04

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRC -453	Clinical Pharmacology	20	20	20	80	--	--	100

Course Prerequisite:

1. Basic knowledge of pharmacology and physiology.
2. Understanding of medical terminology and drug classifications.
3. Familiarity with pharmacokinetics and pharmacodynamics.

Course Objectives:

1. To understand the role and importance of clinical pharmacology in healthcare.
2. To learn the principles of pharmacokinetics and pharmacodynamics for drug dosing and optimization.
3. To gain insights into the design and conduct of clinical trials and drug safety assessment.
4. To explore personalized medicine and future directions in clinical pharmacology.

Course Outcomes:

After successful completion of this course, students should be able to:

1. Explain the process of drug development and clinical trials.
2. Analyze pharmacokinetic and pharmacodynamics data for drug dosing and monitoring.
3. Evaluate drug safety and efficacy in clinical trials.
4. Discuss the potential applications of personalized medicine in healthcare.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Clinical Pharmacology**	15
	1.1	Overview of clinical pharmacology and its significance in healthcare	
	1.2	Drug development process and phases of clinical trials.	
	1.3.	Principles of drug administration and dosing.	
	1.4	Ethical considerations in clinical pharmacology research.	
2.0	**II**	**Pharmacokinetics and Pharmacodynamics**	15
	2.1	Absorption, distribution, metabolism, and excretion of drugs (ADME).	
	2.2	Pharmacokinetic parameters and drug interactions.	
	2.3	Receptor theory and mechanisms of drug action.	
	2.4	Pharmacodynamics variability and individual drug responses	
3.0	**III**	**Clinical Trials and Drug Safety**	15
	3.1	Phases of clinical trials and study design.	
	3.2	Randomized controlled trials and observational studies.	
	3.3	Assessing drug efficacy and safety in clinical trials.	
	3.4	Post-marketing surveillance and pharmacovigilance	
4.0	**IV**	**Individual Variability in Drug Response**	15
	4.1	Pharmacokinetics and personalized medicine.	
	4.2	Drug metabolism and impact on drug response.	
	4.3	Drug dosing in special populations (pediatrics, elderly, pregnant women, etc.).	

	4.4	Factors influencing drug efficacy and toxicity.	
		Total	**60**

References:

1. Lippincott Williams & Wilkins. "Clinical Pharmacology Made Incredibly Easy
2. Laurence L. Brunton, Bruce A. Chabner, and Björn C. Knollmann.. "Goodman & Gilman's The Pharmacological Basis of Therapeutics."
3. Arthur J. Atkinson Jr., John N. McDougal, and Alexander A. Vinks. "Principles of Clinical Pharmacology.
4. Bertram G. Katzung and Anthony J. Trevor.Basic & Clinical Pharmacology"
5. Humphrey P. Rang, Maureen M. Dale, James M. Ritter, Rod J. Flower, and Graeme Henderson. Rang & Dale's Pharmacology.

SCLRP-453 LAB COURSE IN CLINICAL PHARMACOLOGY

1. Pharmacokinetic calculations and dose adjustments based on patient characteristics.
2. Analysis of drug interactions and adverse drug reactions.
3. Evaluation of clinical trial protocols and study design.
4. Ethical discussions on patient participation in clinical trials and informed consent.

SCLRE-451 CLINICAL RESEARCH QUALITY ASSURANCE

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-451	Clinical Research Quality Assurance	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE-451	Clinical Research Quality Assurance	15	15	15	60	--	--	75

Course Prerequisite:

1. Basic knowledge of clinical research principles.
2. Understanding of Good Clinical Practice (GCP) guidelines.
3. Familiarity with data management and analysis.

Course Objectives:

1. To understand the principles and importance of clinical research quality assurance.
2. To learn to plan and conduct quality audits in clinical research settings.
3. To ensure data integrity and compliance with regulatory requirements.
4. To implement effective corrective and preventive actions for continuous improvement.

Course Outcomes:

After successful completion of this course, students should be able to:

1. Develop and implement a quality assurance plan for clinical research projects.
2. Conduct quality audits and identify areas for improvement.
3. Ensure data integrity and compliance with GCP guidelines and regulatory standards.
4. Implement effective corrective actions to address quality issues in clinical research.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Clinical Research Quality Assurance**	11
	1.1	Overview of clinical research quality assurance and its importance.	
	1.2	Roles and responsibilities of quality assurance professionals.	
	1.3.	Ethical considerations and regulatory requirements in quality assurance.	
	1.4	Quality management systems and audits.	
2.0	**II**	**Planning and Conducting Quality Audits**	12
	2.1	Developing a quality audit plan.	
	2.2	Conducting internal and external audits.	
	2.3	Auditing clinical trial sites and research processes	
	2.4	Reporting and addressing audit findings.	
3.0	**III**	**Ensuring Data Integrity and Compliance**	11
	3.1	Data quality assurance and data validation.	
	3.2	Source data verification and validation.	
	3.3	Compliance with protocol and regulatory requirements.	
	3.4	Risk-based monitoring and remote monitoring.	
4.0	**IV**	**Implementing Corrective and Preventive Actions**	11
	4.1	Corrective and preventive action (CAPA) plans.	
	4.2	Root cause analysis and risk mitigation strategies.	

	4.3	Continuous improvement in clinical research processes.	
	4.4	Quality metrics and performance evaluation.	
		Total	**45**

References:

1. Steve S. S. Lee and David T. C. Lin. Quality Assurance in Clinical Trials: A Practical Guide".
2. Brenda R. Dugan and Patricia M. Smith. Managing Quality in Clinical Trials.
3. Duolao Wang, Ameet Bakhai, and Emmanuel Lesaffre. Clinical Trials: A Practical Guide to Design, Analysis, and Reporting.

SCLRE-452 LAB COURSE IN CLINICAL RESEARCH QUALITY ASSURANCE

1. Development of a quality audit plan for a clinical trial.
2. Conducting mock quality audits on research processes and documentation.
3. Data validation and verification exercises.
4. Designing and implementing corrective and preventive action plans.
5. Monitoring and evaluating quality metrics in a clinical research setting.

SCLRE-453 CLINICAL RESEARCH WRITING AND PUBLICATION

Teaching Scheme

Course Code	Course Name	Teaching Scheme (Hrs)		Credits Assigned		
		Theory	Practical	Theory	Practical	Total
SCLRE-453	Clinical Research Writing and Publication	03	--	03	--	03

Assessment Scheme

Course Code	Course Name	Theory				Credits Assigned		Total
		CA			ESA	CA	ESA	
		Test I	Test II	Avg of (T1+T2)/2				
SCLRE -453	Clinical Research Writing and Publication	15	15	15	60	--	--	75

Course Prerequisite:

1. Basic knowledge of clinical research principles.
2. Familiarity with data analysis and interpretation.
3. Understanding of ethical considerations in medical research.

Course Objectives:

1. To understand the importance of effective scientific writing and publication in clinical research.
2. To learn the structure and components of different types of scientific publications.
3. To develop skills in writing research articles, review articles, and case reports.
4. To gain insights into the publication process and ethical considerations.

Course Outcomes:

After successful completion of this course, students should be able to:

1. Write and structure a research article suitable for publication.
2. Prepare review articles and case reports following appropriate guidelines.
3. Navigate the manuscript submission and peer review process.
4. Demonstrate knowledge of publication ethics and best practices.

Curriculum Details:

Module No.	Unit No.	Topic	Hrs.
1.0	**I**	**Introduction to Clinical Research Writing**	11
	1.1	Overview of clinical research writing and its significance.	
	1.2	Understanding different types of scientific publications (research articles, reviews, case reports, etc.)	
	1.3.	Ethical considerations in scientific writing and publication.	
	1.4	Selecting a suitable journal for publication.	
2.0	**II**	**Writing Research Articles**	11
	2.1	Structure and components of a research article.	
	2.2	Writing the introduction, methods, results, and discussion sections.	
	2.3	Citing references and avoiding plagiarism	
	2.4	Tips for effective scientific writing.	
3.0	**III**	**Preparing Review Articles and Case Reports**	12
	3.1	Structure and format of review articles and case reports.	
	3.2	Synthesizing and presenting literature in a review article.	
	3.3	Describing clinical cases and their relevance in case reports.	
	3.4	Peer review process and responding to reviewers' comments	
4.0	**IV**	**Manuscript Submission and Publication**	11
	4.1	Preparing the manuscript for submission.	

	4.2	Dealing with peer review comments and revisions.	
	4.3	Understanding publication ethics and conflicts of interest.	
	4.4	Navigating the publication process and post-publication dissemination.	
		Total	**45**

References:

1. Subhash Chandra Parija.Writing and Publishing a Scientific Research Paper.
2. Robert A. Day and Barbara Gastel. How to Write and Publish a Scientific Paper.
3. American Psychological Association (APA). Publication Manual of the American Psychological Association"

SCLRE-454 LAB COURSE IN CLINICAL RESEARCH WRITING AND PUBLICATION

1. Writing a research article based on a given dataset.
2. Preparing a review article synthesizing information from multiple sources.
3. Drafting a case report based on a clinical case study.
4. Responding to peer reviewers' comments and revising a manuscript.
5. Selecting a suitable journal for publication and preparing the manuscript for submission.

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