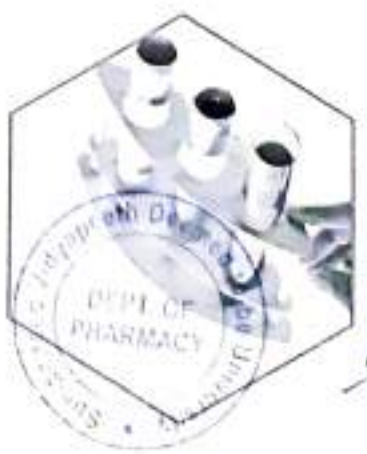
ANNEXURE-1

Department of Pharmacy
Sumandeep Vidyapeeth

An Institution Deemed to be University u/s 3 and 12B of UGC Act 1956
Accredited by NAAC with a CGPA of 3.61 on Four Point Scale at 'A++' Grade in Second Cycle
Category - I Deemed to be University under UGC Regulations 2018
Piparia, Vadodara-391760, Gujarat State, India

Fellowship Program in **Clinical Research**

Duration - 6 Months



Objective:

The Course has been designed to full fill the gap of knowledge among individuals who are related to health care and wish to seek carrier in Clinical research Field. This course will cover all topic which are necessary for the basic as well as advance understanding of the Clinical research.

About the Fellowship:

The course contains detailed guideline of International Council for Harmonisation& Good Clinical Practice (ICH-GCP), which is necessary to ensure the safety, efficacy and quality of medicines developed worldwide. Introduction to the role of Institutional Review Board for maintain ICH-GCP standards in trials being conducted at Hospital under their supervision. Detailed Procedure for the preparation of documents such as Informed Consent form (ICF), Patient Information Sheet (PIS), Adverse drug reaction (ADR) monitoring and reporting, Quality Assurance (QA), Quality Check (QC), Research Protocol, & Record Keeping will be covered in the syllabus. Furthermore, the students will be taught about Research Misconducts, Roles & Responsibilities of various individuals in clinical research, Process of recruitment & Retention, and Investigational New Drugs.

Need of Fellowship:

The subject clinical research is generally not being included in the main course of various health care courses. Since most of the health care professionals are eligible to apply for the jobs related to clinical research, but still are not able to join because of lackingin knowledge relate to field. This is very much needed course to fill this gap and hence will definitely improve the chance of candidate selection in clinical research related jobs and will also improve the quality of clinical trials.

Eligibility:

Candidate shall have passed in following Under Graduate or Post Graduate Program:MBBS, BDS, B. Pharm, BAMS, BHMS, BSc (N), MD/MS, MDS, M. Pharm, Pharm. D, MSc (N), & other equivalent Medical/Paramedical/Science related degree holders are eligible for this Fellowship Program. Students awaiting the final year examination's results are eligible to apply too.

Fellowship Curriculum:

Module	Content	No. of lecture Hours	Duration
1.	Introduction to Clinical Research	02	3 Months
	Institutional Review Board	08	
	Informed Consent	08	
	Confidentiality & Privacy	08	
	Participant Safety & Adverse Events	04	
	Quality Assurance	04	
	Total No. of Hours	**34**	
	The Research Protocol	08	
2.	Documentation & Record Keeping	04	3 Months
	Research Misconduct	04	
	Role & Responsibilities	08	
	Recruitment & Retention	06	
	Investigational New Drug	08	
	Total No. of Hours	38	
	Total Duration	**72 Hours**	6 Months

Evaluation Pattern:

Regular assignment will be given to the student &score obtained in assignment will be added in final score. A MCQ based exam will be conducted and certificates will be issued on the basis of both final exam score and score obtained in assignments.

Benefits of Fellowship:

Healthcare Students who have littleor no exposure to the field of clinical research will acquire necessary knowledge required to continue their carrier in the field of clinical research. Even though they don't want to be a part of clinical research still in their general practice they will be aware of various ethics related to patient which will help them to perform their work more ethically and responsibly.

Outcome:

At the end of the course the students will be able to: (1) Coordinate Clinical Trial, (2) Prepare Protocol (3) Conduct meetings for IRB/IEC, (4) Management of Clinical Research Site (5) Preparation and Maintenance of Clinical trial records (6) Able to recruit for clinical trials, & (7) Application for Investigational New Drug. The scope further increases with the experience in the Clinical research field.

Duration
6 Months
Intake
10
Teaching Platform
Online Lecture and Assignment

Fellowship Co-ordinator

Dr. Hemraj Singh Rajput (Pharm. D)
Associate Professor & I/C Head
Dept. of Pharmacy Practice, DOP
Sumandeep Vidyapeeth Deemed to be University
Piparia, Vadodara.

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Fellowship Program In Clinical Research (Curriculum)

(2023)

Fellowship Program in Clinical Research

1.1 Minimum qualification for admission

Candidate shall have passed in following Under Graduate or Post Graduate Program: MBBS, BDS, B. Pharm, BAMS, BHMS, BSc (N), MD/MS, MDS, M. Pharm, Pharm. D, MSc (N), & other equivalent Medical/Paramedical/Science related degree holders are eligible for this Fellowship Program. Students awaiting the final year examination's results are eligible to apply too.

1.2. Duration of the program

6 Months

1.3. Medium of instruction and examinations

Medium of instruction and examination shall be in English.

1.4. Conduction of Fellowship

The Fellowship shall be conducted from the month of Sep/Oct to Feb/Mar in every calendar year.

1.5. Attendance and progress

A candidate is required to put in at least 75% attendance in total. The candidate shall complete the prescribed course satisfactorily to be eligible to appear for the respective examinations.

1.6 Academic work

A regular record of attendance shall be maintained by the teaching staff of respective courses.

1.7 Course of study

The Fellowship shall include Module wise teaching hours. The number of hours to be devoted to each class shall not be less than that shown in Table – 1

Table-I

Module	Content	No. of lecture Hours	Duration
1.	a. Introduction to Clinical Research	02	3 Months
	b. Institutional Review Board	08	
	c. Informed Consent	08	
	d. Confidentiality & Privacy	08	
	e. Participant Safety & Adverse Events	04	
	f. Quality Assurance	04	
	Total No. of Hours	**34**	
2.	a. The Research Protocol	08	3 Months
	b. Documentation & Record -Keeping	04	
	c. Research Misconduct	04	
	d. Role & Responsibilities	08	
	e. Recruitment & Retention	06	
	f. Investigational New Drug	08	
	Total No. of Hours	**38**	
Total Duration		**72 Hours**	**6 Months**

1.8 Examinations/Assessments

1. Assignment will be given for each module and total marks for each module will be 20 i.e. (2 ×20 = 40). On completion of both module fellows will be awarded marks out of 40 Marks.
2. A 60 marks MCQ based online exam will be conducted.
3. On the basis of Assignment (40 Marks) and Online MCQ exam (60 Marks) i.e., total out of 100 marks a certificate will be issued.
4. The candidate must secure at least 50 marks out of 100 marks for the successful completion of the fellowship.

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Fellowship Program in Clinical Research

72 hours

Scope:

1. Introduction to Clinical Research: This section provides an overview of the field of clinical research, its importance, and its ethical considerations. It covers the principles and regulations governing clinical research, including Good Clinical Practice (GCP) guidelines.
2. Clinical Trial Design and Methodology: This topic focuses on the design and implementation of clinical trials, including study objectives, patient selection criteria, randomization, blinding, and control groups. It also covers various types of clinical trials, such as phase I, II, III, and IV trials.
3. Research Ethics and Regulatory Affairs: This section explores the ethical considerations and regulatory frameworks surrounding clinical research. It covers topics such as informed consent, privacy protection, data management, institutional review boards (IRBs), and regulatory authorities.
4. Data Collection and Management: This topic covers the collection, management, and analysis of clinical research data. It includes data collection methods, case report form (CRF) design, data monitoring, quality control, and statistical analysis techniques.
5. Pharmacovigilance and Drug Safety: This section focuses on monitoring and assessing the safety of investigational drugs and approved medications. It covers adverse event reporting, drug safety monitoring, risk assessment, and pharmacovigilance guidelines.
6. Clinical Research Protocol Development: This topic explores the process of developing a clinical research protocol. It covers research question formulation, study design, sample size determination, study endpoints, and protocol writing.
7. Clinical Research Management: This section delves into the management aspects of clinical research, including study coordination, site selection, investigator responsibilities, patient recruitment, and study monitoring.
8. Good Clinical Practice (GCP) Guidelines: GCP guidelines are a set of international ethical and scientific standards that ensure the integrity and quality of clinical research. This topic covers the principles of GCP, including study conduct, data integrity, and regulatory compliance.
9. Clinical Research Documentation and Reporting: This topic focuses on the creation of essential clinical research documents, such as clinical study reports, investigator brochures, informed consent forms, and regulatory submissions.
10. Emerging Trends in Clinical Research: This section explores the latest advancements and trends in clinical research, such as adaptive trial designs, real-world evidence, precision medicine, and digital health technologies.

Objectives:

1. Understand the Basics: The course aims to provide students with a fundamental understanding of the principles, terminology, and concepts related to clinical research. This includes an overview of the clinical research process, study design, and ethical considerations.
2. Develop Research Skills: The course aims to equip students with essential research skills required in the field of clinical research. This includes skills such as study protocol development, data collection and management, statistical analysis, and critical appraisal of research literature.
3. Gain Knowledge of Regulatory and Ethical Guidelines: Students will learn about the ethical guidelines and regulatory frameworks that govern clinical research. This includes an understanding of Good Clinical Practice (GCP) guidelines, informed consent, patient privacy, data protection, and the roles and responsibilities of regulatory authorities.
4. Understand Clinical Trial Design and Methodology: The course aims to provide a comprehensive understanding of clinical trial design and methodology. Students will learn about the different phases of clinical trials, study objectives, patient selection criteria, randomization, blinding, control groups, and outcome measures.
5. Learn about Safety and Pharmacovigilance: Students will gain knowledge of drug safety and pharmacovigilance in clinical research. This includes understanding adverse event reporting, monitoring drug safety, risk assessment, and ensuring patient safety throughout the trial.
6. Develop Practical Skills in Clinical Research Management: The course aims to develop practical skills required for managing clinical research studies. This includes site selection, patient recruitment and retention strategies, study coordination, monitoring, and quality assurance.
7. Familiarize with Documentation and Reporting: Students will learn how to create essential documents and reports used in clinical research, such as clinical study reports, investigator brochures, informed consent forms, and regulatory submissions. They will gain an understanding of the importance of accurate and comprehensive documentation.
8. Stay Updated with Emerging Trends: The course may aim to expose students to emerging trends and advancements in the field of clinical research. This includes topics such as adaptive trial designs, real-world evidence, precision medicine, digital health technologies, and the use of big data in clinical research.
9. Enhance Critical Thinking and Problem-Solving Skills: The course aims to develop students' critical thinking and problem-solving abilities in the context of clinical research. They will learn how to analyze research data, interpret results, identify challenges, and propose solutions.
10. Prepare for Careers in Clinical Research: Ultimately, the course aims to prepare students for careers in the field of clinical research. This includes providing them with the knowledge, skills, and practical experience necessary to work in roles such as clinical research coordinator, data manager, clinical research associate, or regulatory affairs specialist.

Content

Module-1

Sr. No.	Chapter	Contact Hours
1.	**Introduction to Clinical Research** Definition and Purpose, Historical Background, Ethical Considerations, Types of Clinical Research, Clinical Research Process, Key Stakeholders, Importance of Clinical Research, Challenges and Limitations,	02
2.	**Institutional Review Board** Purpose and Role, Ethical Principles and Regulations, Composition and Membership, IRB Review Process, Risk-Benefit Assessment, Ongoing Monitoring and Reporting, Decision-Making and Appeals, Training and Education.	08
3.	**Informed Consent** Definition and Purpose, Elements of Informed Consent, Capacity to Consent, Consent Process, Special Considerations, Waiver or Alteration of Consent, Inviting Potential Participants to Enroll in a Research Study, Quality Control in the Informed Consent Process.	08
4.	**Confidentiality & Privacy** Introduction, Confidentiality of Clinical Trial Participant Records, Exceptions to Confidentiality Requirements, Maintaining Confidentiality of Research Participants, Certificates of Confidentiality, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, Permitted Disclosures of Protected Health Information, HIPAA Rights, Privacy, and Enforcement.	08
5.	**Participant Safety & Adverse Events** Introduction, Participant Safety & Adverse Events, Assessing an Adverse Event, Adverse Event Reporting, Adverse Event Follow-up.	04
6.	**Quality Assurance** Introduction, QA and Monitoring Role, Trial Monitoring Activities	04

Module-2

Sr. No.	Chapter	Contact Hours
1.	**The Research Protocol** Introduction, Contents of the Research Protocol (ICH E3 GCP 6), Protocol Amendment, Protocol Violation.	08
2.	**Documentation & Record Keeping** Introduction, Documentation Requirements in GCP and Federal Regulations, Examples of Other Sponsor-Required Documents, Documenting the Use of Investigational Drugs.	04
3.	**Research Misconduct** Introduction, Identifying Research Misconduct, Investigating Allegations of Research Misconduct, Responding to Allegations of Research Misconduct, Safeguards for Informants and Accused Persons,	04

	Possible Penalties for Research Misconduct.	
4.	**Role & Responsibilities** Introduction, Roles and Responsibilities of Sponsor, Principal Investigator, Research Site Staff and other roles.	**08**
5.	**Recruitment & Retention** Introduction, Recruitment, Recruitment Strategies, Advertising for Study Participants, Retention, Retention Strategies, using incentives for Study Participation, what to do when a participant leaves a study	**06**
6.	**Investigational New Drug** Introduction, Phase of Clinical Trials of Investigational New Drugs, Investigational New Drugs Requirements, Investigational New Drugs Responsibilities.	**08**

Reference Books:

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 Harmonisation of Technical requirements for registration of Pharmaceuticals for human use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice.E6; May 1996.
3. Ethical Guidelines for Biomedical Research on Human Subjects 2000. Indian Council of Medical Research, New Delhi.
4. Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, March 2005, John Wiley and Sons.
5. Principles of Clinical Research edited by Giovanna di Ignazio, Di Giovanna and Haynes.
6. Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7. Goodman & Gilman: JG Hardman, LE Limbard, 10th Edn. McGraw Hill Publications, 2001.

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