

# SUMANDEEP VIDYAPEETH

(Declared as Deemed to be University under Section 3 of the UGC Act 1956)

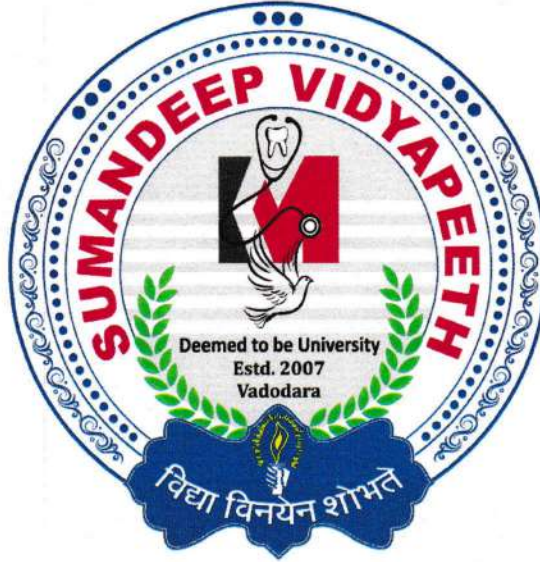
Accredited by NAAC with a CGPA of 3.53 out of four-point scale at 'A' Grade

Category – I deemed to be university under UGC Act - 2018

At & Post Piparia, Tal: Waghodia 391760 (Gujarat) India.

Ph: 02668-245262/64/66, Telefax: 02668-245126,

Website: www.sumandeepvidyapeethdu.edu.in



CURRICULUM

## Diploma in CLINICAL RESEARCH TECHNOLOGY

Attested CTC

*Sharaney* 15/2/2021

Vice-Chancellor

Sumandeep Vidyapeeth

An Institution Deemed to be University

Vill. Piparia, Taluka: Waghodia.

Dist. Vadodara-391 760. (Gujarat)



*Umesh*

*Shankar*



AMENDED UP TO DECEMBER -2020

## INTRODUCTION

### Scope

The quality of paramedical care has improved tremendously in the last few decades due to the advances in technology, thus creating fresh challenges in the field of healthcare. It is now widely recognized that health service delivery is a team effort involving both clinicians and non-clinicians, and is not the sole duty of physicians and nurses. Professionals that can competently handle sophisticated machinery and advanced protocols are now in high demand. In fact, diagnosis is now so dependent on technology, that paramedical and healthcare professionals are vital to successful treatment delivery.

Effective delivery of healthcare services depends largely on the nature of education, training and appropriate orientation towards community health of all categories of health personnel, and their capacity to function as an integrated team, with a range of skills and expertise, play key roles within the National Health Service, working autonomously, in multi-professional teams in various settings. All of them are first-contact practitioners and work across a wide range of locations and sectors within acute, primary and community care.

### Learning goals and objectives for allied and healthcare professionals

The learning goals and objectives of the undergraduate and graduate education program will be based on the performance expectations. They will be articulated as learning goals (why we teach this) and learning objectives (what the students will learn). Using the framework, students will learn to integrate their knowledge, skills and abilities in a hands-on manner in a professional healthcare setting.

### Program outcomes

- The basic concepts of clinical research e.g. what it is, how it differs from standard care and why it is undertaken
- The purpose of ethics in research, what informed consent is and why it is necessary
- Five of the most commonly used study designs
- How high ethical standards, data quality and uniformity are maintained in a study

### Ethics and accountability

Students will understand core concepts of clinical ethics and law so that they may apply these to their practice as healthcare service providers. Program objectives should enable the students to:

- Describe and apply the basic concepts of clinical ethics to actual cases and situations
- Recognize the need to make health care resources available to patients fairly, equitably and without bias, discrimination or undue influence
- Demonstrate an understanding and application of basic legal concepts to the practice employ professional accountability for the initiation, maintenance and termination of patient-provider relationships
- Demonstrate respect for each patient's individual rights of autonomy, privacy, and confidentiality

### Attainment to professional excellence

The student will execute professionalism to reflect in his/her thought and action a range of attributes and characteristics that include technical competence, appearance, image, confidence level, empathy, compassion, understanding, patience, manners, verbal and non-verbal communication, an anti-discriminatory and non-judgmental attitude, and appropriate

**Vice-Chancellor**

**Sumandeep Vidyapeeth**

An Institution Deemed to be University

VII, Piparia, Taluka- Wagholia,

Dist. Vadodara-391 760. (Gujarat)



physical contact to ensure safe, effective and expected delivery of healthcare.

### Eligibility for admission

- Candidate should have passed 10 + 2 with science(PCB)
- Minimum percentage of marks: 55% aggregate.

### Duration of the course

Duration of the course is 2 years +1 year Internship

**Medium of instruction:** English shall be the medium of instruction for all the subjects of study and for examination of the course.

### Attendance

A candidate has to secure minimum 80% attendance in overall with at least-

1. 75% attendance in theoretical
2. 80% in Skills training (practical) for qualifying to appear for the final examination.

No relaxation, whatsoever, will be permissible to this rule under any ground including indisposition etc.

**Assessment:** Assessments should be completed by the academic staff, based on the compilation of the student's theoretical & clinical performance throughout the training programme. To achieve this, all assessment forms and feedback should be included and evaluated. Student must attain at least 50% marks in each Theory, Internal assessment and Practical independently / separately for each individual subject

### COURSE OF INSTRUCTION

Course Name	Course code	Theory (In hrs.) (Class and lab)	Practical (In hrs.) (Clinical)
<b>First Year – total hours-400</b>			
Clinical research Guidelines and Regulations	DRC101	60	40
Clinical Trial Planning and design	DRC102	60	40
Clinical Trial Conduct, Compliance and Quality Assurance	DRC103	60	40
Pharmacovigilance	DRC104	60	40
<b>Total</b>		<b>240</b>	<b>160</b>
<b>Second Year –total hours-400</b>			
Data Analysis and Management in Clinical Research	DRC201	60	<b>40</b>
Clinical Research Management	DRC202	<b>60</b>	40
Basic Safety	DRC203	60	40
<b>Total</b>		<b>160</b>	<b>100</b>
<b>Third Year</b>			
Internship			
		<b>Total hours</b>	

Vice-Chancellor

Sumandeep Vidyapeeth

An Institution Deemed to be University

Vill. Piparia, Taluka- Wagholia.

Dist. Vadodara-391 760. (Gujarat)



## SCHEME OF EXAMINATION

Course	Course Code	Assessment			
		Hours	Internal	External	Total
<b>First Year</b>					
Clinical research Guidelines and Regulations	DRC101	3	20	80	100
Clinical Trial Planning and design	DRC102	3	20	80	100
Clinical Trial Conduct, Compliance and Quality Assurance	DRC103	3	20	80	100
Pharmacovigilance	DRC104	3	20	80	100
<b>Total</b>			<b>80</b>	<b>320</b>	<b>400</b>
<b>Second Year -</b>					
Data Analysis and Management in Clinical Research	DRC201	3	20	80	100
Clinical Research Management	DRC202	3	20	80	100
Basic Safety	DRC203	3	20	80	100
<b>Total</b>			<b>80</b>	<b>320</b>	<b>400</b>

## FIRST YEAR DIPLOMA IN CLINICAL RESERACH TECHNOLOGY

### Clinical research Guidelines and Regulations DRC101

(60 MARKS)

1. Introduction to Clinical Research:
2. Clinical Trial Terminologies
3. History of Clinical research
4. CPCSEA Guideline & Pre-clinical Trials
5. Drug Discovery & Development
6. Role of Clinical Research Organization, Site Management and Monitoring in Clinical Research
7. ICMR (Indian Council of Medical Research ) Guidelines
8. Indian GCP (Good Clinical Practice)
9. ICH GCP (International Conference on Harmonisation)
10. Drug Regulations & Ethics in Clinical Research
11. Background of ethics
12. Declaration of Helsinki
13. Belmont Report
14. Informed consent Process
15. Nuremberg code
16. History of Indian regulations
17. Schedule – Y- Appendices

### Clinical Trial Planning and design DRC102

(60 MARKS)

1. Definition of clinical trial

Vice-Chancellor

Sumandeep Vidyapeeth

An Institution Deemed to be University

Vill. Piparia, Taluka- Wagholia.

Dist. Vadodara-391 760. (Gujarat)



2. Different Phases of clinical research
3. Subtypes of Phase 1,2,3, and 4
4. E –clinical trial
5. Bioavailability & Bioequivalence Studies [BA/BE]
6. CTRI-Clinical trial registry of India

### **Clinical Trial Conduct, Compliance and Quality Assurance DRC103 ( 60 MARKS)**

1. Objectives of a Clinical Research Organization
2. The Definition & responsibilities and duties of Principal Investigator
3. Role of a Clinical Research Organization
4. Role of personnel in a clinical trial

### **Pharmacovigilance DRC104 (60 MARKS)**

1. Drugs & magic remedies Act 1954
2. Drug prices control order
3. Drug Discovery & Development

### **PRACTICALS 40 MARKS**

*Each student shall undergo training in Skill Simulation Laboratory for learning certain basic clinical skills like IV/IM injection, setting IV-line, Cardio-pulmonary resuscitation (CPR), and Life support skills in the beginning of second year, for duration of continuous four days. (Board of Studies letter No.:FPMS/SV/BOS-MIN/0006/2016-17, dated 19/04/2017, and vide notification of Board of Management resolution Ref.:No. SVDU/R/2017-18/5056, dated 09/01/2018). Data*

### **SECOND YEAR DIPLOMA IN CLINICAL RESERACH TECHNOLOGY**

### **Analysis and Management in Clinical Research DRC201 (60- MARKS)**

### **Clinical Research Management DRC202 (60 MARKS)**

1. Assignments and other Activities
2. Clinical Trial Documentation, Audits and Inspections.
3. Clinical trial documents
4. Definition & responsibility of Principal Investigator
5. Audit & inspections
6. Different types of trial design
7. Conduct
8. Medical coding / Writing
9. Close Out
10. Regulations for AYUSH
11. An Introduction to Clinical Data Management
12. Data Management Standards
13. Set Up

**Attested CTC**  
14. CDMS (Clinical Data Management System) & CTMS (Clinical Trial Management System)

**CODE OF PROFESSIONAL CONDUCT**

**Vice-Chancellor**

**Sumandeep Vidyapeeth**

**An Institution Deemed to be University**

**VII, Pipariya, Taluka- Waghodiya.**

**Dist. Vadodara-391 760. (Gujarat)**



## INTRODUCTION

The Code of Professional Conduct is designed and set out as guidance for the clinical practitioner within the relationship that exists with every patient receiving health care.

Essential to that relationship is the patient's trust in the practitioner. This trust hangs upon the patient's assurance of being the practitioner's first concern during their clinical encounter, and upon the patient's confidence that the care received will be competent, whether in diagnosis, therapy or counseling.

## STANDARD OF PRACTICE AND CARE

Patients are entitled to the highest standard of practice and care. The essential elements of this are professional competence, good relationships with patients and colleagues and observance of professional ethical obligations.

### In providing care you must therefore:

- Recognize the limits of your professional competence.
- Be willing to consult colleagues
- Keep clear, accurate and contemporaneous patient records which report the relevant findings
- Keep colleagues informed.
- Pay due regard to the efficacy and the prudent use of resources.
- Be competent, truthful, and accurate, when reporting on investigations.
- Be competent when giving or arranging treatment.

### Patient's rights

- Listen to patients and respect their views.
- Treat patients politely and considerately.
- Respect patients' privacy and dignity.
- Give information to patients in a way they can understand.
- Respect the right of patients to be fully involved in decisions about their care.
- Respect the right of patients to refuse treatment or to take part in teaching or research, reporting the refusal to the person requesting the procedure.
- Respond to complaints promptly and constructively.
- Ensure that your views about a patient's life style, culture, beliefs, race, colour, sex, sexuality, age, social status, or perceived economic worth, do not prejudice the service you give.

## CONFIDENTIALITY

Patients have a right to expect that you will not pass on any personal information which you learn in the course of your professional duties, unless they agree



*Attested CTC*  
*Sharaney*  
*15/2/2021*

**Vice-Chancellor**  
**Sumandeep Vidyapeeth**  
An Institution Deemed to be University  
VIII, Piparia, Taluka: Waghodia.  
Dist. Vadodra-391 700. (Gujarat)