

# SUMANDEEP VIDYAPEETH

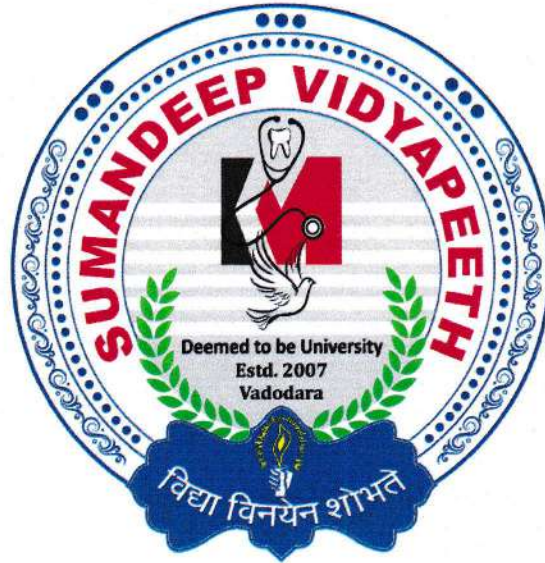
(Declared as Deemed to be University under Section 3 of the UGC Act 1956)

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

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## CURRICULUM

Attested CTC

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15/2/2021

Vice-Chancellor

Sumandeep Vidyapeeth

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Dist. Vadodara-391 760. (Gujarat)

## Bachelor of Science (B.Sc) CLINICAL RESEARCH



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2016



## 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 paramedical 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. These learning goals are divided into nine key areas, though the degree of required involvement may differ across various levels of qualification and professional cadres.

### Program outcomes


Clinical research is a branch of healthcare science that determines the safety and effectiveness of medications, devices, diagnostic products and treatment regimens intended for human use. These may be used for prevention, treatment, diagnosis or for relieving symptoms of a disease.

### 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

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- Demonstrate respect for each patient's individual rights of autonomy, privacy, and confidentiality

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

### **Eligibility for admission:**

1. He/she has passed the Higher Secondary (10+2) Science or a duly constituted Board with pass marks in Physics, Chemistry, Biology
2. Diploma in Radiology Imaging Technology with minimum aggregate of 50% marks.

### **Duration of the course:**

Duration of the course is 4 years including 1 year internship.

### **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.

### **Medium of instruction:**

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

### **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.

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### COURSE OF INSTRUCTION

Course Name	Course code	Theory (In hrs.) (Class and lab)	Practical (In hrs.) (Clinical)
<b>First Year – total hours-400</b>			
Pharmacology	BCR101	60	40
Clinical Research	BRC102	60	40
Medicine	BRC103	60	40
Biostatistics	BRC104	60	40
<b>Total</b>		<b>240</b>	<b>160</b>
<b>Second Year –total hours-400</b>			
Pharmacology	BRC201	60	<b>40</b>
Clinical Research	BRC202	<b>60</b>	40
Medicine	BRC203	60	40
Biostatistics	BRC204	60	40
<b>Total</b>		<b>160</b>	<b>100</b>
<b>Third Year – total hours 600</b>			
Pharmacology	BRC301	160	40
Clinical Research-I	BRC302	120	80
Clinical Research-II	BRC303	120	80
<b>Total</b>		<b>400</b>	<b>200</b>

### SCHEME OF EXAMINATION

Course	Course Code	Assessment			
		Hours	Internal	External	Total
<b>First Year</b>					
Pharmacology	BCR101	3	20	80	100
Clinical Research	BRC102	3	20	80	100
Medicine	BRC103	3	20	80	100
Biostatistics	BRC104	3	20	80	100
<b>Total</b>			<b>80</b>	<b>320</b>	<b>400</b>
<b>Second Year -</b>					
Pharmacology	BRC201	3	20	80	100
Clinical Research	BRC202	<b>3</b>	20	80	100
Medicine	BRC203	3	20	80	100
Biostatistics	BRC204	3	20	80	100
<b>Total</b>			<b>80</b>	<b>320</b>	<b>400</b>
<b>Third Year -</b>					
Pharmacology	BRC301	3	20	80	100
Clinical Research-I	BRC302	3	20	80	100
Clinical Research-II	BRC303	3	20	80	100
<b>Total</b>			<b>60</b>	<b>240</b>	<b>300</b>

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## FIRST YEAR B.SC IN CLINICAL RESEARCH

### BCR101-PHARMACOLOGY

60 HOURS

#### **Introduction to Pharmacology**

Definitions and brief – (pharmacology, pharmacokinetics, pharmacodynamics, drug, pharmacotherapeutics, clinical pharmacology, chemotherapy, pharmacy and toxicology), drug Nomenclature (chemical name, non-proprietary name and proprietary name) and essential drugs concepts

#### **Routes of Drug Administration**

Local routes (topical, deeper tissues and arterial supply etc.), systemic routes (Oral, sublingual, rectal, coetaneous, inhalation, nasal, parenteral etc.)

#### **Dosage Forms of Drug –**

Definition and brief about the dosage forms – solid dosage forms (powder, tablets, capsules, lozenges, pills, cachets), liquid dosage forms (suspension, emulsion, elixirs, syrups, lotions, inhalations, eye drops, ear drops, enemas, mouth washes etc.), semisolid dosage forms (ointments, creams, pastes, gels, suppositories, etc.), sterile products (Injection, ophthalmic etc.), gas (aerosols, inhalations, sprays etc.) and novel drug delivery system (liposome, nano some, nanoparticles, microspheres, osmotic pumps, transdermal, implants, intrauterine devices)

#### **Sources of Drugs –**

Natural sources and synthetic sources

#### **Pharmacodynamics:**

Principles of drug action and mechanism of drug action, dose response curve and adverse drug reaction

#### **Factors Modifying Drug Action**

Body size, age, sex, species and race, genetics, environmental factors, psychological factor, pathological states, other drugs, cumulation, tolerance, etc.

**Pharmacokinetics** – brief of absorption, distribution, metabolism and excretion

**Autonomic nervous system** - Introduction, cholinergic system, anti-cholinesterase,

### BCR102-CLINICAL RESEARCH HOURS

60

#### **Introduction to Clinical Trials**

Necessary of terms in clinical trials, history, requirements, new drug development process, need for new drug, selection of a chemical compound as a potential drug, screening of

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chemical compounds, translation medicine, assessment of preclinical data **Phases of clinical trials.**

### **Principles of controlled clinical trials-**

Clinical trial design (observational and interventional) protocol, consent in clinical trials, placebo, bias and methods to prevent bias, ethics in clinical trials, monitoring, problems and solutions of controlled clinical trials. Multicentre clinical trials- Requirements, regulations and feasibility. Improving patient enrolment and retention in Clinical Trials

### **Other Clinical Studies**

Pharmacoepidemiology, pharmacovigilance, ADR monitoring, pharmacokinetic trials, quality of life studies

### **Legal issues in clinical trials**

### **Drug regulations**

National- good clinical practice and schedule Y

Critical evaluation of literature- Systematic review and meta-analysis, evidence-based medicine

## **BCR103-MEDICINE**

**60 HOURS**

**Note: brief study of the following topics with their relevant applications**

### **Introduction to clinical medicine**

Science and art of medicine, global issues in medicine, screening and prevention of diseases

### **Basic climatic and environmental diseases**

#### **Diabetes mellitus**

Functional anatomy, physiology, presenting problems in Diabetes mellitus, management, drugs-class effect and side effects, dietary management, long term complications in brief

#### **Hypertension**

Definition, types of hypertension, causative factors, pathophysiology, JNC classification of Hypertension, dietary management, treatment (different classes), class effect and side effects

#### **Coronary artery diseases**

Ischemic heart disease ; definition , types, causative factors, path physiology, life style modifications, treatment (different classes) ,class effect and side effects in brief

#### **Cerebrovascular diseases**

Stroke etiology, management; life style modifications, treatment (different classes), class effect and side effects in brief

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**BCR104-BIOSTATISTICS  
HOURS**

**60**

**Introduction-** Biostatistics and standard terminology

**Basic knowledge about presentation of data**

Type of diagram, one dimensional diagram, two-dimension diagram, three-dimensional, pie diagram and pictogram

**Graphic representation of data**

Histogram, frequency, polygon and frequency curve.

**Sampling** - Definition, selection of samples, merit and limitation of sampling, methods of sampling.

**Measures of central tendency**

Mean, median, mode and relation between arithmetic mean, geometric mean and harmonic mean.

**Measures of dispersion**

Mean deviation, advantage and disadvantage of mean deviation, coefficient of mean deviation, standard deviation, application of standard deviation and coefficient of variation.

**Definition and application**

Correlation, regression, Chi-square test and t-test.

**Communication**

Types of communication, pronunciation, consonants and vowel sounds, grammar, noun, adjectives, use of definite and indefinite articles, tenses. Vocabulary; antonyms, synonyms, homonyms, one word substitution, common phrases and idiomatic expressions

**SECOND YEAR B.SC IN CLINICAL RESEARCH**

**BRC201-PHARMACOLOGY  
HOURS**

**60**

**Histamine**

Classification of drugs, prototype drug- actions, prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

**Antihistamine**

Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

**Drugs acting on kidneys and GIT:**

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## **Diuretics**

Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

## **Antidiuretics**

Classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

## **Drugs for peptic ulcer**

Introduction to disease in brief, classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

## **Cardiovascular Pharmacology:**

### **Hypertension**

Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

**CHF:** Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

### **Coronary Artery Disease**

Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

### **Arrhythmia**

Introduction to disease in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

### **Endocrine**

### **Pharmacology:**

#### **Diabetes Mellitus**

Introduction to disease in brief, insulin – types of insulin, class effect and side effect, methods to deliver insulin, management of acute complication of diabetes, oral hypoglycemic drugs- classification of drugs, class effect and side effect, peculiar effect and side effect of some important drugs

#### **Thyroid hormone and Thyroid inhibitors**

Anatomy & physiology of thyroid in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

**Corticosteroids-** Anatomy & physiology of adrenal gland in brief, classification of drugs, prototype drug- actions, Prototype drug- class effect and side effect, peculiar effect and side effect of some important drugs

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**Estrogen, Progestins and Contraceptives-** Classification of drugs, prototype drug-actions, class effect and side effect, peculiar effect and side effect of some important drugs

**Oxytocin and other drugs acting on uterus-** Classification of drugs, prototype drug-actions, class effect and side effect, peculiar effect and side effect of some important drugs,

**Drug affecting calcium balance-** Physiology of calcium balance in brief, classification of drugs, prototype drug- actions, class effect and side effect, peculiar effect and side effect of some important drugs

## **BRC202-Clinical Research HOURS**

**60**

**Toxicity studies** – Acute, sub-acute and chronic toxicity studies, Detail of Acute, sub acute and chronic toxicity studies, Mutagenicity, Carcinogenicity and Teratogenicity

**Quality Assurance/Quality Control studies:** Guidelines and operational techniques

### **Drug regulations:**

International: Food and Drug Administration and European Medicine Agency.

- Introduction of FDA
- History of FDA and Departments in FDA
- Regulations in FDA
- Regulations in FDA
- How FDA works
- introduction of European Medicine Agency

**Clinical Data Management-** Introduction, planning of trial, database, flow of data, creating database, Data Validation, system validation, data entry, E- data capture.

**Therapeutic drug monitoring** - Efficacy and safety measurement, endpoints

**Auditing:** Research Auditing & Inspections

**Preparing Clinical Trial Report:** Interim study report, close out report

**Case Record Form:** Introduction to CRF, Format and Sponsor Needs, guidelines related to CRF filling

**Research ethics and research audits:** Declaration of Helsinki

**Ethical issues in Genetic Research:** Genetic engineering, Gene mapping, cloning and ethical issues

**Research methodology (laboratory and clinical)** - Definition, objectives, concept, variable

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Research process, research question – Hypothesis, features of a good research design.

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**Experimental Design-** Concept of independent & dependent variables

**Exploratory Research Design** – Descriptive vs analytical Research, applied vs fundamental research, qualitative vs quantitative research

**Use of tools / techniques for research-** Methods to search required information effectively and teaching of latest software to search data and facilitate writing for publications e.g. Endnote

**Funding Medical Research** – Budgeting of a clinical trial in detail

**Business Process Outsourcing and Contract Research Organization-** Organizational structure, Types, Relationships with various stakeholders in the Clinical trial process

**Overview of Pharma. Business-** India and worldwide: Introduction, Major Pharma players: global & Indian, their area of research market scenario of health care products

**Business Development-** Introduction, methodology and importance

**Translational medicine-** Introduction, methodology and importance

**Conflicts of Interest-** Investigator, sponsor, publisher

**Community based Qualitative Research and Research Ethics-** Ethical Principles, informed consent, confidentiality of information shared and anonymity of research participants, no harm to participants, beneficence and reciprocity

**Facilitating Best Practices**

- Introduction to Standard operating procedures (SOP's) & need for SOP
- Training and decision-making

**BRC203-MEDICINE  
HOURS**

**60**

**Arthritis- Rheumatoid arthritis, osteoarthritis-** Definition, pathophysiology, treatment - different classes of drugs, class effect and class side effect, pharmacological-classification of drugs, class effect & class side effect & non-pharmacological treatment

**Shock** - Definition, pathophysiology, types of shock, presenting features, diagnostic investigation in brief, pharmacological- classification of drugs, class effect & class side effect and non-pharmacological treatment

**Inflammatory Bowel Disease and Irritable Bowel Syndrome-** Definition, pathophysiology, presenting features, management, investigation, pharmacological-classification of drugs, class effect & class side effect & non-pharmacological treatment

**Heart failure, Coronary artery diseases:** drugs, surgical treatment in brief & stents

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**Common infections:**

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- **Tuberculosis** – causative agents, diagnostic criteria, etiological agents in brief, categories of tuberculosis, classification of drugs, first line drugs in detail different classes of drugs, class effect and class side effect , DOTS therapy, multidrug resistant tuberculosis
- **AIDS** - Etiological agents in brief, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment regimes, prophylactic therapy, therapy in pregnancy
- **Malaria**- Life cycle of causative agent, types of malaria, causative agents, diagnostic criteria, treatment, different classes of drugs, class effect and class side effect treatment of relapsing malaria, treatment of cerebral malaria, multi drug resistant malari

## BRC204-BIOSTATISTICS 60 HOURS

**Probability:** Definition and Application

**Parametric Tests:** Definition and Application  
**Analysis of variance-One Way and Two Way**

- McNamara's test
- Exact probability test

**Rank score tests** – Definition and Application

- Wilcoxon signed ranktest,
- Wilcoxon two sample ranktest,
- The Mann Whitney Test,
- The Spearman Test,
- The Friedman Test.

**F-test** – testing of two population variances

**Study design and choosing a statistical test Design-Assignments**

**Practical Lab (Part I-IT & Part- II Communication and management)**

**MS- Excel** – Introduction to excel and RDBMS

**Clinical Data Management** – Overview, regulation, data management plan, data aquacition and CRF designing, database designing and implementation, data entry and verification and data analysis.

**Soft Skills** - Introduction and definition, motivation, SWOT analysis, goal setting, business etiquettes, business dressing, business communication, understanding body language and gestures, listening skill, giving and accepting feedback, group discussion.

- Introduction
- Working with SAS Data Sets
- Working with Raw Data Files
- Creating Variables

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- Manipulating Data
- Generating Reports
- Getting started with SAS
- Getting familiar with SAS Data Sets
- Producing List Reports
- Enhancing out put
- Creating SAS Data Sets
- Data step Programming
- Combining SAS Datasets
- Producing Summary Reports

## MANAGEMENT

**ACCOUNTING** - Basic accounting, Accounting principles & conventions, Accounting Terms, Types of accounts, Accounting Rules , Double Entry, Ledger Posting, Trial Balance, Final Accounts

**MARKETING** - Marketing Concept, Marketing environment, Marketing mix, Market Segmentation, Consumer behavior, Advertisement, Pricing policy, Ethical and social

## Communication English

- **Grammar usage** – Pronoun, Problems in grammar usage, Transitive and Intransitive Verb,
- Singular and plural verbs, Adverb
- **Vocabulary usage**- How to Keep Your Sanity with transitive and intransitive verbs
- Interview Skills
- **Reading Assignments**
- **Writing Assignments**

## THIRD YEAR B.SC IN CLINICAL RESEARCH

**BRC301-PHARMACOLOGY  
HOURS**

**60**

**Introduction, classification, mechanism of action and side effect of the following categories of drugs:**

- General Anesthetics
- Sedative and Hypnotics
- Antiparkinsonian
- Antipsychotic
- Antidepressant

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**Opioid analgesic and antagonist** - introduction to pain pathway in brief and classification of drugs, prototype drug- actions, side effect of some important drugs

**Antimicrobials** — introduction, classification, mechanism of action and side effect of the following categories of drugs:

- Sulfonamides
- Cotrimoxazole and Quinolones
- Beta-Lactam Antibiotics
- Tetracycline & Chloramphenicol
- Amino glycosides antibiotics
- Macrolide, lincosamide, glycopeptides, & other Antibacterial Antibiotics
- Antitubercular drugs
- Antileprotic drugs
- Antiviral drugs
- Antimalarial drugs
- Antiamoebic drugs
- Antiprotozoal
- Antihelminthic drugs

**Immunomodulatory drugs**- introduction, classification, mechanism of action and side effect of Immunomodulatory drugs

**Anti-cancer drugs** - introduction, classification, mechanism of action and side effects of anti- cancer drugs

**BRC302-CLINICAL RESEARCH HOURS**

**60**

### **Bioavailability /Bioequivalence Studies**

Introduction, terminology, concepts, characteristics and regulatory guidelines in India.

### **Introduction to GLP and GCP, Declaration of Helsinki**

### **Regulations for pre-clinical and clinical studies and drug regulation:**

- DCGI
- Indian Council of Medical Research
- FDA
- OECD
- WHO
- National Institute for Clinical Excellence (NICE), European Medicines Agency

**Pharmaceutical marketing** - introduction to

- Medico marketing
- Industry scenario

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- Pharmaco economics

**Special clinical trials and trial related issues** - special population, trials on special population, and trials on life threatening diseases (ICH Guidelines).

**Micro-dosing** - Phase 0 and importance in relation to clinical research

**Biomarkers** – definitions, importance, surrogate biomarkers

**Health Insurance Portability and Accountability Act (HIPAA)** - introduction to HIPAA, titles under HIPAA, privacy rule, PHI.

**BRC303-CLINICAL  
60 HOURS**

**RESEARCH**

**Clinical Data Management** - communication, query process, coding dictionaries, locking of database, process after database locked, publishing, data management: career prospectus

**Intellectual Property rights (IPR)** - copyright, trademarks, patents: requirement, objectives, patent implications, recent scenario and case studies

**Patents Regulations** - trade related aspects of intellectual property rights (TRIPS), patent extension rules, implications

**Pharmacovigilance:**

- Methods of pharmacovigilance, causality assessment
- International Guidelines – US, UK and timelines of ADR reporting

**Medical Transcription** – introduction, process of transcription in context of clinical

**Inspection** - introduction, responsibilities of clinical trial staff, and actions: before, during and after completion, action item list

**CONSORT:** Consolidated Standards of Reporting Trial

**Trial master file** - contents of master file, source document, compilation, documentation, ways and importance

**Publishing Research Studies:** publication of research paper/report in National and International Scientific journals and ethics

**Confidentiality and competitiveness in clinical trial**

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## guidelines

### INTERNSHIP (INTEGRATED PRACTICE) -

TOTAL HOURS 1440

- The internship will span 1 Year. This will include 6 hours of practice a day, totaling to 1440 hours during internship year. As a part of this, the students will maintain a work logbook which will be duly endorsed by the supervisor or trainer. At the end of internship, the candidate shall submit the work log book along with certificate from the training institute.
- The internship time period provides the students the opportunity to continue to develop confidence and increased skill in clinical delivery of services. Students will demonstrate competence in beginning and intermediate procedures. Students will observe the advanced and specialized procedures. The student will complete the clinical training by practicing all the skills learned in classroom and clinical instruction. The students are expected to work for minimum 6 hours per day and this may be more depending on the need and the healthcare setting.

### CODE OF PROFESSIONAL CONDUCT

### 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.

#### Patients' rights

- 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.

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- 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.

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