APHETA
INSTITUTE OF CLINICAL RESEARCH

Texila American University

PhD. in Clinical Research

Campus

Critchlow, Woolford Avenue, Georgetown, Guyana, South America
Telephone : (+592) 2318118, Fax : (+592) 2318111, Web : www.tauedu.org

Study Centre

Apheta Institute of Clinical Research
201, 2nd Floor, South Ex. Tower, Masjid Moth, South Ex. Part – 2, New Delhi – 110049
Email Id : info@aicrindia.com
Website : www.aicrindia.com
Phone: +91 11 45782279

ABOUT TEXILA AMERICAN UNIVERSITY

Texila American University (TAU) is located in Guyana, the only English-speaking country in South America. TAU offers Health Science programs with a high level of professionalism, exactness and problem solving skills, upon which the foundations of specialist training and an independent medical practice can be built, which facilitates further education and development of their knowledge throughout their life.

The curriculum at the TAU is structured after the best U.S. medical schools. The academic program is both accelerated and rigorous, with a focus on preparing students for licensure in the United States, Caribbean and India. The Program curriculums are designed to reinforce the enduring tenets of the practice of medicine and ensure the ability of understanding and handling the changing demands of heath service in the various fields of society

Students at TAU are presented with, and challenged to adopt, the ethics and values that apply to all health professions. Putting the patient first, improving the lives of the underserved, emphasizing health care for rural populations, celebrating diversity wherever we find it and developing cultural competency are all essential to the daily practice of health professionals.

In clerkships students acquire in-depth clinical experiences to sharpen their communication and healthcare problem-solving abilities. Students are advised to participate in an outreach & volunteer programs where they receive practical training in delivering health care services.

TAU offers full-time programs in MD-Medicine, Dentistry, Nursing, Pharmacy and other Allied Health Science programs. TAU also offers PhD in Clinical Research through on line learning. TAU operates on a system in which classes begin in January June and October.

ABOUT GUYANA

Living in Guyana is a wonderful experience and would be one of the finest environment and climatic conditions for your studies. Guyana is an amazing blend of the Caribbean and South America and is the only English speaking Country in South America. The beautiful country is a tropical paradise and has much to offer; adventure, tranquility, history, beauty, nature and an inimitable blend of warm and friendly people with the richness of many cultures.

The Republic of Guyana lies in the north-east of South America, north of the equator. It is bordered by Suriname on the east, Brazil on the south and Venezuela on the west, and to the north and east, extends to the North Atlantic Ocean.

The coastal plain, along which the majority of the population lives, is flat but the country is famous for its mountain ranges, lush forests, vast savannahs and above all the majestic Kaieteur Falls with an overall drop of 251 meters and a sheer drop of 226 meters. It is richly endowed with natural resources, extensive areas of fertile agricultural land, vast stretches of tropical hardwood forests most of which are still untouched, a rich fishing and scrimping continental shelf, a wide variety of minerals (including gold, diamond and some semi-precious stones, bauxite and manganese) impressive resources for hydropower generation and potential for petroleum

WHY TAU

- Texila American University is recognized by NAC and is also going for various accreditations worldwide like WHO , FAIMER and IMED
- Texila American University is having MOU's with various CRO's and hospitals in USA and Brazil. Hence the university delivers the not only the course but organize clinical rotation for the student if needed
- Texila American University provides dual degree programs in association with University of Guyana which is the top ranked university in Guyana
- Mou's are signed with hospitals like Georgetown Public Hospital Corporation (GPHC), which is rated as the best hospital in the country
- Certification by a premier university recognized globally
- Courses designed and developed by experts in clinical research
- Teaching by experienced professionals from industry and academia

SELECTION PROCESS /CRITERIA

Will be based on Merit / Interview:

The selection process will be open, transparent and accountable. Every applicant who fulfils the eligibility criteria will be given an opportunity to compete for the available seats.

TEACHING METHODOLOGY

The courses will have regular classroom lectures, seminars, readings, tutorials, group discussions, assignments, case presentations, home work and lectures by eminent guests from academia and industry.

EVALUATION CRITERIA

1) Internal Assessments:

Internal assessment comprises of two internal tests and one assignment in each subject. Maximum weight age for internal assessment is 40% of the total marks in each subject.

2) Course End Final Examination:

The weightage for the Final examination will be 60% of the total marks for each subject.

AWARD OF CERTIFICATES

Candidates who successfully complete the course and pass the examination will be awarded relevant Certificates by Texila American University.

PhD. in Clinical Research

Duration: 36 Month (6 Semester)

Total course Fees: 7200 USD (2400 USD/Year) Scholarship is available on the basis of their experience, qualification and personal interview

Registration Fees: 220 USD which is included in total course fee.

Mode of Learning: Online Learning with the help of Webinars, Video Lectures and Audio Lectures. The guide will be provided to the students who will guide through online and chat.

Credit: 90 (60 Theory + 30 Thesis)

Credit Distribution for theory subject: 40 Credit from basic and core subject and 20 Credit from Optional Subject

Eligibility: PG Students of Medicine / Life Science / Pharmaceutical / Nursing / Allied Health Science / Clinical Research.

Process of Application: Eligible candidate can download the application form from the website

http://www.aicrindia.com/images/Application%20form%20PhD_Texila%20American%20University.pdf

After filling the application form student need to send this form and copy of the academic certificate till master degree along with mentioned registration fee by cash or DD in

Favor of **"APHETA EDUCATIONAL TRUST, NEW DELHI"** to the following address.

APHETA INSTITUTE OF CLINICAL RESEARCH
No. 389, South Ex. Tower, 201, 2nd Floor
Masjid Moth, South Ex. Part II
New Delhi – 110049, India
Ph. No - 011-45782279

Candidate can also pay the registration fee by using net banking or Bank Transfer. The details are as follows:

Bank Name	: HDFC Bank
A/C Name	: Apheta Educational Trust
A/c No.	: 03192000008789
IFSC code	: HDCF0000319
Branch	: South Extension part - 2, New Delhi, India

The certificate will be sent to the Texila American University for the confirmation of the eligibility.

On confirmation letter which will be received in a week from the Texila American University Student need to submit the remaining fee of 1st year before commencement of the course.

Please check the following document before sending the application

1) 4 passport size Photographs
2) Curriculum vitae (signed by the candidate)
3) Filled application form
4) Registration Fee (As mentioned above)

Following Documents to be notarized and **the true copy of the notarized** are to be sent along with above mentioned documents.

1) O level
2) A level
3) Passport-copy
4) Bachelors transcripts
5) Bachelors certificate
6) PG transcripts
7) PG certificate
8) Any other certificate

Notarization: The documents will be made a copy and attested by a gazetted officer / public authority / Lawyer.

SYLLABUS FOR PhD.

1. Biomedical - Pathophysiological Basis of Diseases: (3 Credits)

Pathophysiology of Diseases of, Neurological, Cardiovascular Haematological, Respiratory, Renal, Gastrointestinal, Endocrine system, Lymphatic system, musculoskeletal system, Reproductive and Endocrine system

2. Pharmacology and Pharmacotherapeutics –I: (3 Credits)

Basic Principles of Pharmacology, Mechanism of Drug action, Adverse Drug Reactions, Pharmacogenetics and Pharmacogenomics. Drugs acting on Autonomic nervous system, Central nervous system, Cardiovascular, Haematological, Respiratory, Gastrointestinal ,Renal, Endocrine Lymphatic, Musculoskeletal Reproductive systems . Pharmacology of Autocoides

3. Pharmacology and Pharmacotherapeutics – II: (3 Credits)

Pharmacology of Antimicrobial and Chemotherapeutic Agents, Antineoplastic agents, Immunosuppressants and Immunostimulants, Hormones and Antagonists, Dermatologic and Ocular agents.

4. Drug Discovery and Drug Development Process: (2 Credits)

History of Drug Discovery and Drug development Process. Strategies, Techniques and Approaches employed in Drug Discovery, New Chemical Entity Identification. Preclinical and Clinical studies, Ethical and Regulatory Issues.

5. Fundamentals of Biostatistics: (1 Credit)

Fundamentals of Statistical Concepts applicable to Medical and Clinical Research. Application of various Statistical Analysis Methods, Research Designs to Data commonly encountered in the Biological, Clinical, and Medical studies and Research. Basic concepts in Statistics which includes Sampling procedures , Presentation of Data, Descriptive and Inferential Statistics, Probability, Confidence Intervals, Hypothesis testing, Regression, Parametric and Non-parametric methods and Design of Experiments.

6. Introduction to Clinical Trials: (2 Credits)

History of Clinical Research, Phases of Clinical Trials. Responsible Persons involved in the Trial. Trial Process from Initiation to close out. Randomization, blinding, Regulatory and Ethical aspects, Audit, Monitoring. Responsibilities and duties of Organizations and Personnel involved in Clinical Trials.

7. Principles and Practice of Clinical Trials: (3 Credits)

Historical, Ethical and Regulatory Foundations of Current Requirements for Research involving Human Subjects. Detailed Clinical Trial Process. Primary and Secondary Objectives of Clinical Research. Protocol Development and writing of Clinical Research Protocols, SOPs, IND, NDA Applications for Approval. Introduction to Essential Documents. Practices including Trial Designs. Analysis and interpretation of Clinical Trials Data. Safety Monitoring Boards, FDA Regulations, Patient Recruitment and Retention and Exclusion. Responsible persons involved in Data management in clinical trial.

8. Regulatory Affairs in Clinical Trials: (2 Credits)

Issues Relating to Regulatory Legislations, Indian GCP guidelines (Schedule Y), USFDA, ICH, GCP and ICMR Guidelines, Regulatory Guidelines of European Union and Japan. Responsibilities of Sponsor, Investigator, IRB/IEC, Monitor, CRA, CRC. Detailed description of Essential Documents, Investigational New Drug Application [IND], New Drug Application [NDA]

9. Bioethics – Ethical Aspects of Clinical Trials. (2 Credits)

Ethical aspects in the Practice of Clinical Research. An overview of the tragedies of the past. Establishment and organization of ethics committees / IRB, Informed Consent. Ethical Principles of Autonomy, Beneficence, Nonmaleficence , justice and application of these Principles to Clinical Research involving Human Subjects. Use of Unproven Therapies, Placebos, Consent process, IRB submission and Review Processes.

10. Clinical Data Management: (3 Credits)

Collection of Data and their Management prior to Analysis. Data Management Plan, CRF Design Considerations. Data Cleaning, Data Processing, Data changing Issues. CRF Tracking, Managing Lab Data. Collecting Adverse Event Data. Creating Reports and Transferring Data and Discrepancy Management. Necessary infrastructure, SOPs and Guidelines, System validation, Test Procedures etc. Data Management Systems. EDC [Electronic Data Capture], Coding Dictionaries, Migrating and Archiving Data. Quality Control and Quality Assurance etc

11. Pharmacovigilance and Safety: (2 credits)

Basic Concepts and Definitions, Scope and Epidemiology of Adverse Events. Product Recall and Withdrawal of Drugs with specific examples and Drug related Deaths, Causality Assessment, Dechallenge and Dechallenge, Periodic Safety Update Reports, Pre and Post Market Risk Management. Responsibilities of Stake holders. Regulatory Reporting Norms of different Nations.

12. Quality Control, Audit and Inspection in Clinical Trial: (2 Credits)

Introduction to Quality in Clinical Research. Quality control and Quality Assurancs of the Conduct of Clinical Trials. Auditing and Monitoring of Sponsor. IRB, IEC. QA and QC tools for Audits, Preparation and Conduct of Audit. Process Mapping. FDA, EMEA, MHRA, DCGI Inspections.

13. GCP/GLP/ICH.for Doctors, Pharmacists and Nurses: (2 Credits)

Introduction to Clinical research and Phases in clinical research. Principles of Good Laboratory Practices (GLP) and Good Clinical Practices (GCP). Indian GCP, ICH. ICMR Guidelines, Declaration of Helsinki, Ethical Considerations. Regulatory Guidelines of other Countries. Responsibilities of Sponsor, Investigator, IRB/IEC, Monitor, CRA, CRC. Detailed Description of Essential. Documents, Investigational New Drug Application [IND], New Drug Application [NDA].

14. Research Project; (10 - 15 Credits):

Project Report under the Guidance of Investigator in Clinical Trial Environment.

15. Medical writing / Reporting: (2 Credits)

Principles involved in writing and Reporting Clinical Trial Results General writing skills, Writing Scientific Abstracts. Anatomy of a Research Article, Submitting and Revising Papers for Publications. Oral Presentations, Use of Audio - Visual Aids, Power Point and Poster Presentation etc.

16. IPR - Intellectual Property Rights: (2 Credits)

IPR law in India, US, Europe and Japan. Filing and Protection of Patents, Copy Rights, Trade Marks, Copy Rights, Trade Marks, Patents etc.

17. Communication Skills: (2 Credits)

Soft Skills Training, Personality Development Training, Communication and Interpersonal Skills, Goal Setting, Public Speaking Skills, Leadership Skills. Team Building, Stress Management and Time Management

18. PK, BA, BE In Clinical Trials: (2 Credits)

Design and Conduct of PK studies. Types of BA/BE Studies. Methods to Determine BA /BE, Factors influencing BA / BE. Comparative Clinical Trials. Documentation and Facilities for conducting BA/BE Studies, Maintenance of Records and Retention of Samples.

19. Epidemiology: (3Credits)

Principles and Concepts of Epidemiology and Methods for Assessing factors associated with the Distribution and Etiology of Diseases. Research Study Design. Case Series and Cross Sectional Studies, Cohort Studies, Case Control Studies. Measures of Association, Bias, Confounding, and Interactions. Epidemiology of Communicable and Non - communicable Diseases.

20 .Molecular Biology and Biotechnology: (3 Credits)

Structure and Functions of Cell Organelles. Cell Division and Apoptosis. Structure and Propertiesz of DNA, Discovery of DNA as the Genetic Material. Concept and Definition of the Genome, C - Value paradox, Denaturation and Renaturation of DNA, Repetitive and Non Repetitive DNA.

Prokaryotic And Eukaryotic Genome Organization. Organization of Viral and Bacterial genome. Definition of gene, Open Reading Frames. DNA Replication in Prokaryotes and Eukaryotes. Regulation of DNA Replication. Gene Mutation, types of Mutation. Mutagenic Agents. DNA Repair Mechanisms, DNA Recombination. Gene Expression, RNA Transcription, Translational Controls. Regulation of Gene Expression, Operon Concept. Regulatory, Promoter, Operator and Structural genes. Role of CAMP and CRP in Gene Expression, Oncogenes and their Properties.

21. Pharmaceutical Biotechnology: (3 Credits)

Pharmaceutical Biotechnology and its future role in healthcare.

Pharmaceutical Applications of Enzymes. Enzyme Immobilization: Various techniques, immobilization of cells and enzymes and their therapeutic applications. Recombinant DNA technology: Production of Recombinant Pharmaceuticals: Insulin, Human Growth Factor, Factor VIII, Interferon’s Etc.

A brief introduction to immunology. Monoclonal antibodies and Hybridism technology. Formation and selection of Hybrid Cells, Principles and productions of monoclonal Antibodies, Synthetic Peptide Vaccines, Recombinant Antigen Vaccines, New generation Vaccines : Preparation and Standardization, Principles of multivalent subunit vaccines

Genetic disorders and gene therapy: Single gene disorders, its molecular genetics, common diseases, antoimmune diseases, cancer, cardiovascular diseases, nervous disorders. Gene therapy: current Gene therapy of genetic disorders like cystic fibrosis, Thalassaemia, Neuroblastoma, hepatitis, AIDS, diabetes, hemophilia B etc.

22. Computer Aided Drug Designing: (3 Credits)

Bioinformatics in Drug Development; Chemo informatics and Pharmacoinformatics. Applications of Drug Discovery and In - Silico Drug Designing Structure□based drug designing approaches: Target Identification and Validation, homology modeling and protein folding, receptor mapping, active site analysis and pharmacophore mapping, Grid maps. Ligand-based drug designing and Docking Ligand-based drug Designing approaches: Lead Designing, Combinatorial chemistry, High Throughput Screening (HTS), QSAR, Database Generation and Chemical libraries, Introduction to docking methods to generate new structure; Tools and Molecular docking programs:

23. SAS Programming: (2 Credits)

SAS procedures for Data Analysis, Data Relationships, producing data, probability, study of randomness, introduction to interference, interference for distribution, inference for proportion, inference for two way tables, inference for regression, one way and two way analysis of variance, logistic regression, parametric and non parametric tests.

24. Seminars: (1 - 6 Credits)

25. Assignments (1 - 6 credits)

CREDIT DISTRIBUTION

BASIC SUBJECTS		
Code No.	**Subject**	**Credit**
CRB001	Biomedical / Pathophysiological basis of Diseases	3
CRB002	Pharmacology and Pharmacotherapeutics I	3
CRB003	Pharmacology and Pharmacotherapeutics II	3
CRB004	Drug Discovery and Drug Development	2
CRB005	Fundamentals of Biostatistics	1
CORE SUBJECTS		
CRC006	Introduction to Clinical trials	2
CRC007	Principles and Practice of Clinical trials	3
CRC008	Regulatory affairs in Clinical Trials	2
CRC009	Bioethics-Ethical aspects in Clinical Trials	2
CRC010	Clinical Data Management	3
CRC011	Pharmacovigilancee and safety Management	2
CRC012	QC , Audit, Inspection in Clinical Trails	2
CRC013	GCP/GLP/ICH	2
CRC014	Research Project in Clinical Trails	10 - 15
OPTIONAL SUBJECTS		
CRO015	Medical writing / reporting IPR	2
CRO016	Intellectual Property Rights	2
CRO017	Communication skills	2
CRO018	PK,BA,BE in Clinical studies	2
CRO019	Epidemiology	3
CRO020	Molecular Biology and Biotechnology	3
CRO021	Pharmaceutical Biotechnology	3
CRO022	Computer Aided Drug Designing,	3
CRO023	SAS Programming	2
CRO024	Seminars	1 - 6
CRO025	Assignments / Tutorials	1 - 6

For further enquiry contact on the following Address:

Apheta Institute of Clinical Research
No. 389, South Ex. Tower, 201, 2nd Floor, Masjid Moth,
South Ex. Part – 2, New Delhi – 110049
Phone: +91 11 45782279, Email: info@aicrindia.com
Website: www.aicrindia.com