TRANSLATIONAL HEALTH SCIENCE AND TECHNOLOGY INSTITUTE

THSTI-JNU PhD PROGRAM

Pre-PhD Course work

The students admitted to THSTI-JNU PhD program will be required to undertake courses to earn 14 credits to be eligible to undertake thesis research work. THS-1, THS-2, and THS-3 are core courses of 8 credits and compulsory for all students. All other courses are optional and the student has the choice to earn 6 credits by choosing any combination. The courses offered over the two semesters are:

SEMESTER-I

1.	Biomedical Research : Concepts and Methods	THS-1	3 credits
2.	Clinical Research Methodology	THS-2	3 credits
3.	Research Internship	THS-3	2 credits

SEMESTER-II

1.	Health Policy and Decision Analysis in Health	THS-4	2 credits
2.	Infectious Disease Biology	THS-5	2 credits
3.	Infectious Disease Epidemiology	THS-6	2 credits
4.	Immunology and Immunotechnology	THS-7	2 credits
5.	Special Topics in Epidemiology	THS-8	2 credits
6.	Essentials of Clinical Trials	THS-9	2 credits
7.	Essentials of Regulatory Trials	THS-10	2 credits
8.	Introduction to Biodesign	THS-11	2 credits

Minimum grade required for obtaining credits in any individual course will be 'B' equivalent to a numerical value of 5 on a 10-point scale. A minimum CGPA (Cumulative grade point average) of 6.5 (6.0 in case of SC/ST and disabled students) is required for successful completion of Pre-PhD registration course program. Only those who successfully complete the pre-PhD registration course will be recommended for the confirmation for the PhD course registration and allowed to undertake thesis research.

For further details, students are advised to refer to the ordinance relating to the award of degree of doctor of philosophy by Jawaharlal Nehru University, New Delhi.

THS-1 (3 CREDITS)

BIOMEDICAL RESEARCH : CONCEPTS AND METHODS

This course has been designed to introduce the students to the practical world of life science research. The curriculum covers fundamental concepts of basic and translational research as well as educates them in identifying and executing innovative research ideas. The course also allows students to gain theoretical and practical understanding of techniques relevant to modern day life science research.

The course will cover the following topics:

I. Introduction to Basic and Translational Research
Translational research: Ethics and Challenges
Identifying a research idea / problem, Designing and writing a research proposal
The publication process : Writing skills and plagiarism
II. Genetic engineering and Molecular Biology Techniques
Recombinant DNA technology: Cloning, restriction and modification enzymes
Prokaryotic and Eukaryotic cloning and expression vectors
Polymerase chain reaction (Techniques and application)
Gene sequencing
RNA analysis: RNA isolation, cDNA preparation, RT-PCR, microarray, transcription kinetics analysis
Northern hybridization; Southern hybridization
DNA-Protein interaction analysis: EMSA, ChIP
Genomic library construction
Protein expression and targeting
Mammalian cell culture, transfection and reporter assay
Protein-protein interaction study: Yeast two hybrid, mammalian two hybrid, pull down assay, co-immunoprecipitation.
III. Biochemical, Biophysical and Imaging Techniques
Introduction to biochemical techniques
Biochemical strategy for cell fractionation, organelle separation
Centrifugation techniques
Electrophoresis (Agarose, PAGE, IEF, 2D)
Chromatography (Principle, type, application; practical demo of FPLC)
Introduction to spectroscopy: Principle and application of UV-Visible spectroscopy
Atomic spectrophotometry, NMR and IR spectroscopy
Basics of light & fluorescence microscopy, Confocal Microscopy & its applications

Advanced applications of confocal microscopy (FRET/FLIM/FRAP etc.)
Specialized microscopy techniques (Multiphoton and super resolution imaging)
Electron Microscopy
IV. Bioinformatics, Functional and Metagenomics Tools
Basics of Bioinformatics
Biological databases/webservers and their usage
Analysis of nucleic acid and protein sequences and secondary structure prediction
Clustering and phylogeny
Homology modelling of proteins
Energy minimization
Protein-ligand and protein-protein interactions
Docking and molecular dynamics
Transgenic technology: Knock-in, Knock-out methods
Transgenic technology: Constitutive, Conditional ablation or expression
RNAi: Principle and application
Next generation sequencing
Introduction to Systems Biology: Basics of systems biology approach and network generation

THS-2 (3 CREDITS)

CLINICAL RESEARCH METHODS

Students across life science disciplines require a sound knowledge of the fundamentals of research methods to understand, design, analyze and communicate their research. Students will be exposed to the basics of the components of a good research proposal and the essential epidemiological and statistical concepts that form the framework of sound research. Students will learn to use simple designs and statistical methods to formulate questions and analyze data. In addition to lectures and seminars the course will involve multi-faculty workshops, exercises in biostatistics with STATA statistical software and group tasks. Students across diverse fields are expected to understand the basics of clinical research methods and the language of clinical research by the end of the course.

The course will cover the following topics:

Role of Biostatistics in Clinical Research
Identifying a research question
Basic study designs
Concepts in Descriptive Statistics
Concepts of Inferential Statistics • Hypothesis testing • Estimation
Epidemiology in the framework of disease • Epidemiological concepts, transmission of disease • Use of morbidity and mortality indices in epidemiologic studies/disease surveillance
Biostatistics: Parametric, Non parametric test, correlation
Concept of regression
Introduction to statistical software (STATA) • General Guidelines in Data entry • Data Management • Preparing data for analysis in STATA
Workshops on Epidemiology and Biostatistics
Ethics in Research

THS-3 (2 CREDITS)

RESEARCH INTERNSHIP

Students are required to work in the lab/clinic of the assigned supervisor in the afternoon and undergo training in various research methodologies and participate in laboratory/clinical discussions. At the end of the semester, students are required to write a report (8-10 pages) on various tasks assigned and make a presentation on their accomplishments to the assessment committee. The supervisor will provide his/her assessment of the student's performance during the internship, participation in laboratory/clinical activities and discussions, and the quality of report. Students are also expected to fine tune their analytical and scientific communication skills by presenting a seminar on a relevant topic (in consultation with their supervisor), detailing the existing knowledge and their opinion about future perspectives on that topic.

HEALTH POLICY AND DECISION ANALYSIS IN HEALTH

Application of solutions for public health in the real world requires robust decision-making and analysis of risks. Economic analyses of policy decisions become even more critical in contexts of constrained resources. Public health professionals will be trained in techniques of decision and risk analyses. Many of these techniques can be used at the bedside as well for population & community health decisions. These methods can also be adapted to decision making for research priorities, outcomes and funding. Bayesian probability, evaluation of diagnostic tests, decision trees, QALYs, disease burden quantification, utilities and cost effectives analysis are some of the topics that will be covered. The course will involve lecture sessions with active class participation, in-class and take home exercises.

The course would cover the following topics:

Probability
Assessing tests   • Sensitivity, Specificity, Positive and negative predictive values   • Likelihood ratios   • Screening tests   ROC curves
• Utilities – standard gambles, time tradeoffs, QALYs
Cost effectiveness analysis – shopping spree, competing choices
Decision Trees
Burden of disease estimation
Policy decisions in health
Decision making in research

THS-5 (2 CREDITS)

INFECTIOUS DISEASE BIOLOGY

This course aims at educating students about important human infectious diseases prevalent in India and worldwide. Introductory lectures by clinical experts on few important infectious diseases will provide a practical overview of those diseases from a doctor's point of view. Further emphasis will be given to understanding the molecular basis of various bacterial and viral infections. This course will also cover classical as well as modern approaches to developing prophylactic and therapeutic strategies against those pathogens.

The course would cover the following topics:

Infectious disease biology : The clinicians' perspectives
Infectious diseases in developing countries (Diseases covered: Tuberculosis, Diarrhea, HIV-AIDS, Cholera)
Introduction to bacterial infectious diseases
Bacterial classification, structure, niche and life style
Antibiotics and drug resistance
Bacterial strategies and arsenal for subversion of host-mediated insult
Methodologies of understanding bacterial pathogenesis, animal models
Understanding host-pathogen interactions
Systems biology of infection and host-pathogen crosstalk
Gut microbiota and human health
Introduction to virology: History, definitions, host specificity of viruses, cell culture and animal models, infectious clones
Virus host range: tissue tropism and its implications for disease outcome
Virus structure: Viral diversity with respect to structures and factors governing viral capsid assembly and packaging
Viral life-cycle: Virus-host interactions in cellular entry, pathways involved in virus entry
Role of viral and cellular factors in virus replication, assembly and egress
Replication of viral genomes, Baltimore classification, host factors influencing viral replication host factors influencing viral replication
From virus isolation to drug development – focus on techniques: Isolation of viruses, titering assays, diagnostic tests, antiviral assay development
Antiviral response and immune-evasion strategies by viruses: Stages of viral life-cycle that trigger immune response, modulation of MHC I and II levels, interferon responses, specific examples of viral immune evasion
New and emerging viruses of public health importance, successful vaccines, vaccines of the future, novel ideas and approaches in vaccine development

THS-6 (2 CREDITS)

INFECTIOUS DISEASE EPIDEMIOLOGY

This course covers advanced topics in epidemiology covering infectious disease dynamics, the spread of infections and the investigation of outbreaks, vaccines and other infectious disease control strategies as well as the basics of mathematical modeling of infectious diseases. The course will consist of lectures, seminars, and reading material. In addition, a number of in-class and take home exercises will form a strong component of the course. Students will also spend substantial time in group-activity across disciplines to learn to work collaboratively to formulate translational research questions and to design studies to answer them. Students will be expected to present seminars in the course.

The spread of infectious diseases • Infectious disease dynamics • The reproductive number • Mathematical modeling of infectious diseases
Control & eradication of infectious diseases • Outbreaks – surveillance and investigation • Eradication of an infectious disease – the small pox story • Control strategies – vaccines and other strategies
Emerging infectious diseases

THS-7 (2 CREDITS)

IMMUNOLOGY AND IMMUNOTECHNOLOGY

This course covers both theory and techniques relevant for immunological research. The first part of the course aims at explaining the fundamental concepts of immune system and its components and illustrate the importance of these under various conditions such as infections, cancer or transplantation therapy. The course also covers the importance of human microbiome in mediating immune functions. The second part of the course will cover theoretical and practical aspects of techniques important for immunological research in the laboratory as well as discuss the concepts of important diagnostic techniques.

Overview of the immune system. Innate Immunity, Adaptive Immunity in the context of cells and organs.
Generation of B-cell and T-cell Receptors: Antigens, Antibodies, Organization and expression of immunoglobulin genes. The Compliment system. The major histocompatibility complex and antigen presentation. T-cell receptor. T-cell generation. T-cell activation and differentiation. B-cell generation, activation and differentiation.
The Immune system in health and disease: Immunity to virus and bacteria. Immunity to fungi and parasites. Immunodeficiency and AIDS. Cancer and the immune System. Tolerance and autoimmunity. Transplantation immunology. Experimental systems.
Cytokines and cytokine receptor signaling: Cytokines and their types. Cytokine receptors family. Cytokine receptor signaling, JAK-STAT signaling pathways. Effector functions of cytokines in health and disease.
Microbiome and mucosal immunity
ELISA, ELISPOT, RIA, FACS
Immunoelectrophoresis
Hybridoma Technology
Immunization protocol and antibody generation
Phage display
Generation of antibodies using synthetic antibody libraries
Luminex based ELISA
In-vitro diagnostic (IVD) concept, types, market
Immunoassay concept, formats and platforms, labels
Binder-target interaction in Immunoassay
Nucleic acid detection: concepts and platforms

THS-8 (3 CREDITS)

SPECIAL TOPICS IN EPIDEMIOLOGY

This course covers advanced topics in epidemiology providing detailed understanding of the design and implementation of cohorts and case control studies as well as other epidemiologic studies. The course will consist of lectures, seminars, and reading material. In addition, a number of in-class and take home exercises will form a strong component of the course. Students will also spend substantial time in group-activity across disciplines to learn to work collaboratively to formulate translational research questions and to design studies to answer them. Students are expected to participate in discussions in classes.

The course will cover the following topics:

Study designs
• Cohort and case-control studies
• Advanced study designs
•   Crossover studies
•   Stepped wedge designs
• Incorporating biological research into clinical research designs
Quality in clinical research
Nutritional Epidemiology
• Collecting nutritional data
• Macronutrients
• Micronutrients in public health
Vitamin A and child health
Zinc in human health
Vitamin D and calcium
Other vitamins and minerals

THS-9 (3 CREDITS)

ESSENTIALS OF CLINICAL TRIALS

This course addresses critical methodological aspects of clinical trials. At the end of this course the student will be able to demonstrate understanding of the principles of clinical trials, assess and select relevant research designs for clinical trials, conduct random allocation, blinding and sample size estimations, critically interpret published results from clinical trials.

General principles of clinical trials
Eligibility criteria, randomisation, allocation concealment and blinding
Sample size for adequate precision and power
Intervention, comparator (Placebo/Standard Care)
Ascertainment of outcome
Data collection (questionnaire design, field organisation, training & standardisation) & quality control
Data management and study implementation
Analysis plan, intention to treat analysis, data exploration, baseline comparison, main effects, hypothesis tests & precision of effect
Interaction and confounding
General principles of community based clinical trials
Challenges of community based clinical trials
Case study of a vaccine trial conducted in the community
Operational aspects
Ethical considerations: vulnerable population with emphasis on administration of informed consent
Some critical aspects of data management
Setting up a data management system for community trials

THS-10 (2 CREDITS)

REGULATORY TRIALS

This course is designed to create awareness about the regulations & guidelines related to clinical research in India as well as globally. The students will understand how to manage a clinical study effectively by good documentation and clinical data management practices. The course prepares the participants to face audit and regulatory inspections from regulatory agencies.

The course would cover the following topics:

Regulations & Guidelines for Clinical Research - India & International (Indian GCP, ICH GCP, ICMR Guidelines, Schedule Y, Declaration of Helsinki)
Drug Development & Clinical Research (Chemistry, Animal Toxicology, Animal Pharmacology, Phase of Clinical Research)
Ethical Requirements & Regulations
Responsibilities of all Stakeholders
Clinical Study Management (Planning, Initiation, Recruitment, Retention of Subjects, Study Monitoring, Close out, IMP Management, Clinical Trial Documentation & Archival)
Safety Monitoring & AE Reporting
Clinical Data Management
QC, QA, Regulatory Inspections

THS-11 (2 CREDITS)

INTRODUCTION TO BIODESIGN

This course provides a semester-long introduction to the Biodesign process for medical technology innovation. As an introductory course, students will get exposure to the first two of the 3 "I's" of the Biodesign process, viz. "Identification" (of unmet needs) and "Invention" (of need-specific technology solutions). Students will be structured into multi-disciplinary teams which will work on real-life solutions to problems in national health priorities, both in diagnostics and therapeutics. Alumni from the Stanford-India Biodesign Program and experts from the med-tech industry will be invited to deliver talks and lectures on special topics.

Starting with a clinical strategic focus area, the course will train students in identifying unmet needs through a clinical immersion program followed by rigorous and systematic analysis and filtering. Student teams will then focus on the top unmet need in diagnostics or devices, and invent novel, need-specific technologies. They will then develop preliminary prototypes of their novel technologies and present these to a jury of experts from industry and academia at the end of the semester. The course will also briefly introduce additional translational requirements for the third step of med-tech innovation, viz. "Implementation", including intellectual property management, regulatory processes and business-plan development. Teams with the most compelling projects will get continued expert mentoring, training and support to translate their ideas into real-life technology products for patient use beyond the end of the course.

The course will cover the following topics.

I.	Identification
	Clinical Immersion and Problem Identification
	Consolidating Unmet Needs
	Needs Filtering and Identification of Top Unmet Clinical Need
	Needs Specification
II.	**Invention**
	Concept Generation
	Concept Selection
	Product Design and Rapid Prototyping
III.	**Introduction to Implementation**
	Intellectual Property
	Regulations in medical technology
	Market Research and Stakeholder Analysis
	Business Plan Development