Translational Health Science and Technology Institute

(THSTI)

THSTI Genesis

The visionaries who were impassioned by the urgent public health concerns that faced the nation helped the conceptual creation of Translational Health Science and Technology Institute in 2009. The emphasis was on fast tracking health care solutions that would meet the needs of a fast developing economy which lacked the health care intensity. THSTI was mandated to move knowledge derived from basic research to the bedside and further to the community. In the three years that have followed since its inception, THSTI has developed rapidly with a zeal that is seldom seen in the corridors of learning.

Created as an autonomous institute by the Government of India, under the Department of Biotechnology, Ministry of Science and Technology, THSTI is an important component of an emerging cluster of institutes known as the NCR Biotech Science Cluster, situated in Faridabad. The cluster is an ambitious initiative that aims to create an unique institutional ecosystem for the conduct of multidisciplinary research.

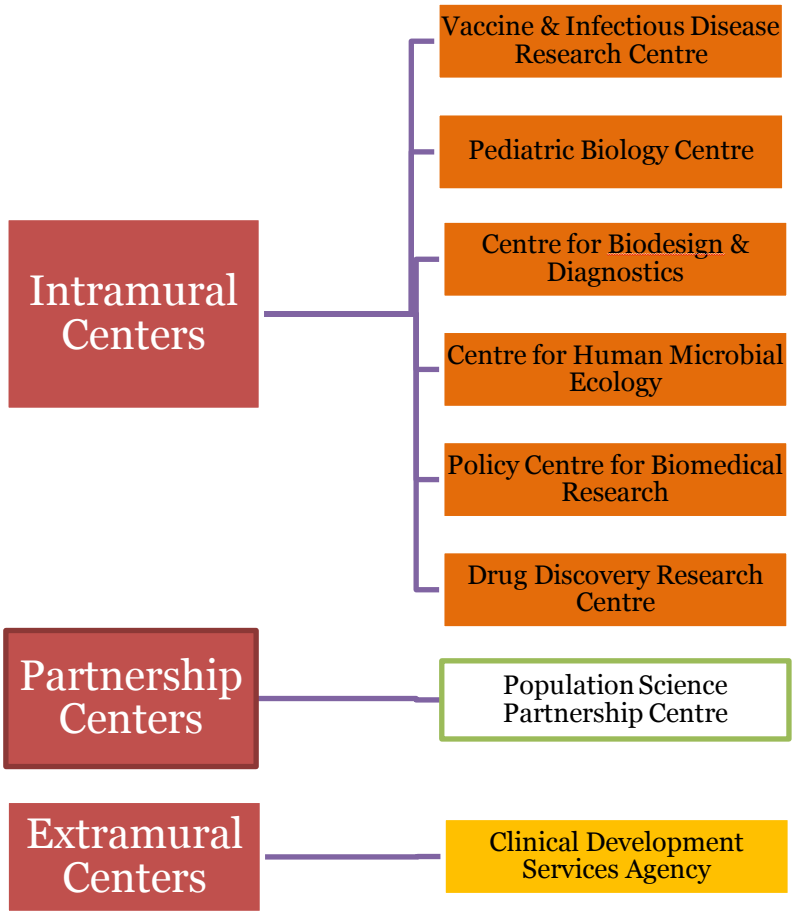
THSTI Mission

The THSTI mission is to integrate the fields of medicine, science, engineering and technology into translational knowledge that would result in biomedical innovations accessible to public health, and improve the health of the most disadvantaged people in India and throughout the world. The focus will be on diseases with the highest burden.

THSTI Organizational Structure

THSTI has a network structure that consists of individual program centres that function within an overarching administrative management. Although the centres represent theme-specific focal points they additionally conceptualize, implement and communicate programs in their inter-connectedness and wholesomeness. THSTI essentially follows a divisional organizational structure with these self-contained centres. Each centre operates as a separate cost and revenue unit; incorporates functions/expertise that operate towards a specific biomedical sub-domain; houses further super-specialization within each group; and uses delegated authority.

Organogram of THSTI



The centres are supported by a growing number of service, technology, clinical development and research to policy support platforms. These are detailed below and are at different stages of development:

- Clinical research management systems
- Clinical Research Unit at the Gurgaon General Hospital, District Haryana
- High throughputs labs for clinical development
- Translational platform at the Biotech Science Cluster
- Animal facility
- Support systems for devices and diagnostics; product validation labs, antibody engineering facilities
- Advanced data analysis
- Infrastructure for bio repository
- Advanced platforms for microbiome analysis

THSTI Functioning

The affairs of the THSTI are managed, administered, directed and measured, subject to rules, bye-laws and orders of the Governing Body. Administrative and financial management are compliant with the Government of India rules and guidelines.

The day to day operations of the institute is managed by a set of functional committees steered by the Institute Management Committee.

Issues pertaining to management of human resource and research facilities, streamlining of both intra- and inter-centre research themes, optimal utilization of resources, and other such matters are overseen by the Institutional Management Committee to ensure efficient operation.

For regulatory compliance, the Institutional Human Ethics committee, the Institutional Animal Ethics Committee and the Institutional Biosafety Committee direct relevant research processes.

THSTI is mentored by a Scientific Advisory Group of Experts (SAGE) who engages with the institute leadership and faculty on issues relevant to enhancing scientific productivity and innovation aligned to the institute's mission. This is supported by the centre or the program specific Scientific Advisory Groups (SAG) that are responsible for in depth evaluation of programs specific to individual centres. In addition, for collaborative or network programs that span centres and/or institutions, special scientific advisory groups that may include international participants are constituted. This is in addition to the oversight groups that are set up by DBT and other funding agencies that support our major programs.

Operation and sustainability of the Program Centres

As stated above the idea underlying the centres is to coalesce individual and team efforts around a domain area and to seed inter-centre and inter-institutional programs. The challenge now is sustainability and connectedness among centres; rather than functioning as siloes. For sustainability, the Governing Body of THSTI has approved a mechanism where at the end of a five year term, each center will go through a rigorous external evaluation by DBT and a fresh SFC proposal with rationale, objectives and justification for continuing the scientific and non-scientific staff of the program will be submitted to DBT. The scientific and non-scientific staff will get appropriate new contractual offer at a respective level of qualification and experience. For long-term stability of the centers, THSTI will provide core faculty, funds for equipment and consumables from the core THSTI funds. A concurrent proposal, as recommended by the Governing Body may be submitted to the Ministry for converting at least 2-3 program positions to core faculty positions to facilitate further expansion of the program.

Models of Translational Research

THSTI thrives to experiment and establish various models of translational set-up for enhancing innovation in biomedical research in each of its program centres. One such model is an

enterprise model where the premium is on achieving defined goals in a time-bound manner. While such an approach provides relatively less freedom to the investigators to indulge in curiosity-driven research questions it, nonetheless, is becoming increasingly relevant given the highly competitive nature of the current public-private scenario. An alternate model is that which encourages innovation through collegial integrated conversation, and provides more freedom to individual researchers in centres with targeted basic discovery research. For THSTI, a balanced multi-model translational set-up is envisaged for the initial years.

Specifically, the process research and development can be visualized to involve the following stages:

1. Ideas for R and D emerge in one of the following ways:

    - By the individual scientists
    - Opportunity landscaping at the institutional, DBT or the global level
    - Industry contributed ideas
    - Invitations to join the global network
    - Through immersion fellowships (e.g. biodesign)

2. The R and D gets carried out in different ways depending on the stage and nature of research on the innovation pathway:

    - **Targeted discovery:** Individuals or small team
    - **Early translational:** Expanded teams within/across centres/institutions
    - **Clinical development:** Large inter-centre inter institutional teams often with public private partnerships
    - **Mega programs:** Large teams, inter-institutional, network based with active participation of funding agencies.

THSTI Research Programs

Programs are driven by a science strategy and ideas, are non-territorial, encouraged by bi-directional feedback loops of T1-T4, to create learning circles and complementing skill circles. The overall impact to a field is better communicated as a cross-sectorial program. The programs enable THSTI to better communicate and contribute to a field.

Programs are also multi-disciplinary and involve several centres at THSTI, adopting a functional matrix structure. Each program addressing a specific scientific area is evolved by integrated contribution by several centres on their functional domain. For example, the program for pre-term birth has components from PBC, CHME, CDSA contributing to their relevant domains of expertise; collaborates with other non-THSTI centres; has a separate governance for cost and revenue management and assessment. But the coordinator of this program is assigned

to oversee the cross- functional aspects of the project, while the functional or centre heads maintain control over their resources and project areas.

This structure provides simultaneous focus on multiple perspectives, and makes a centre responsive to more than one innovation initiatives. This introduction of multiple perspectives is expected to improve the time frame and quality of innovation, providing ability for the organization to change and adapt along with challenges emerging from the environment.

These multi-centre multi-disciplinary programs also enable the organization to benefit from the social/personal resource (e.g. personal networks, cross-functional trust and shared values) that drives sustainable innovation.

At THSTI, we believe, that there is no 'typical' or 'definite' roadmap for a successful organizational structure and governance for enhancing translation. We are constantly striving to explore conventional and unconventional mechanisms that can define and shape up the future of this organization, and this new experiment.

THSTI faculty and their scientific and academic roles

THSTI has a dual cadre of faculty, (i) Core faculty and the (ii) Program faculty.

Core faculty:

The core faculties are those hired against the cabinet-approved regular positions and are designated Assistant Professor, Associate Professor or Professor. They are group leaders and principal investigators (PIs) of their research groups.

Qualification, scientific and academic responsibility, tenure track after appointment: For appointment as Assistant Professor, Associate Professor and Professor, a candidate with a non-medical background requires a productive post-doctoral experience of a minimum of 3 years, 7 years and 14 years respectively and for candidates with a medical degree a minimum experience of 3 years, 7 years and 14 years following their post-graduation, besides fulfilling other criteria defining the breadth and quality of their research experience. The faculty is expected to develop and lead research programs that are within the mandate of THSTI as defined in the section on THSTI research program. They are assigned PhD students for mentoring directly under their own supervision. This would require their recognition by the university to which the PhD students would register.

Tenure of appointment: They will follow a tenure track and will move to the next senior position based on the Flexible Complementary Scheme.

Program faculty

The Program Research Scientists are those who are appointed on contract in SFC approved research programs and are designated as Research Scientist C, Research Scientist D or Research Scientist E. The program scientific faculties are taken on contract for a period of 5 years or for the period of the research program whichever is earlier.

Qualification, scientific and academic responsibility, tenure of appointment:

Appointment as a Research Scientist C requires 1-2 years of post-doctoral experience (or 1 year experience after post-graduation for medical scientists). Appointment as a Research Scientist D and Research Scientist E requires a minimum of 3 years/7 years of productive post-doctoral experience for scientists with a non-medical background and for candidates with a medical degree a minimum experience of 3 years / 7 years following their post-graduation.

A Scientist C is expected to bring to the research group their specific research experience and broaden their research abilities while working with the senior group leader. Their research is supported by the resources available to the research group where they work but can generate extra-mural grants for supporting their research, provided it is within the mandate of the program. In situations where the funding agency considers only scientists D and above as PIs, they can apply as co-PI. Research Scientist C is not assigned the responsibility of mentoring PhD students but s/he could be a member of the advisory committee of THSTI PhD students.

A Scientist D or E will work independently on programs that are within the mandate of the Centre assisted by JRFs, SRFs or research associates. Based on their demonstrated scientific progress, and their ability to manage the scientific manpower, assessed by the group leader over at least a year, they are assigned to mentor PhD students as co-guides along with their group leader. They can mentor PhD students as chief guides if the university that is granting degree allows them to register as independent PhD guides. At this stage, they are also encouraged to write grants as a PI in domain areas of the centre.

Tenure of appointment: The Program faculty will be reviewed at the end of 2 years to decide if the positions will be further extended so as to complete a full tenure of 5 years. After 5 years they are evaluated & based on the satisfactory review of their performance, and the renewal of the grant, new contracts will be given at an appropriate level that commensurate with their past performance and experience as recommended by the review committee. The program faculty can also be considered for absorption into the core faculty through a rigorous evaluation process as done for the recruitment of the other core faculty.

It is implicit that the performance evaluation criteria for all scientific appointments will take into account the responsibility assigned, general expectations at the level of the position held, and the scientific and academic output. Where the performance review is not up to the expectation, the scientist appointed through any of the above tracks may be given a one-year extension of contract to allow him/her to wind up their on-going work and seek other avenues.

Project Scientists

In addition to the two types of faculty as mentioned above, project scientists and senior project scientists are part of an extramurally funded research program led by a PI. Their research is supported by the resources available to the research projects where they work and, therefore, are not required to generate extra-mural grants for supporting their research. These scientists may be supported with a JRF or a technician based on their progress and requirements assessed by the group leader. The equivalent positions in clinical projects are medical research officers, senior research officers and clinical coordinators. These medical officers are supported by field staff, nurses, and technicians. These scientists/research officers/senior research officers/clinical coordinators are not assigned the responsibility of mentoring PhD students but s/he could be a member of the advisory committee of THSTI PhD students.

The performance evaluation criteria for these scientific appointments will take into account the responsibility assigned, general expectations at the level of the position held, and the scientific and academic output. Their terms of the contract will be governed by the THSTI administration.

Measurable outputs of research for faculty and scientist:

1. Disease biology insights:

- Knowledge of disease mechanisms
- Targets for new therapeutics
- Leads to diagnosis and interventions
- The outcomes are usually publications and ideas for early translation

2. Early translation

- Proof of principle to decide whether to move to product innovation
- New tools for R and D, biomarkers for downselection of multiple candidates, lead compounds, optimized compounds, potential immunogens, animal models for research, as spinoffs

3. Late translation

- This extends up to Phase I trials for early leads from targeted discovery or external knowledge
- Potential candidates-pilot lots, toxicology, continued lead optimization, pharmacokinetics, extended proof of principle with new outcomes

4. Clinical development under partnership

- Phase II, III trials
- Post marketing surveillance

5. Policy for diffusion of affordable technology

6. Other outputs:

- Development of physician scientists
- Influence medical and drug translational science in the country
- Developing affordable products and technology either through entrepreneurial initiatives of the faculty or through collaboration with industry.

THSTI-JNU PhD program

THSTI runs an academic program to train graduate students towards their doctoral degree. THSTI has recently been recognized as an institute where students could pursue research towards their doctoral degree to be awarded by the Jawaharlal Nehru University (JNU), New Delhi.

The THSTI-JNU Academic Committee (AC) constituted by the THSTI Executive Director with JNU's concurrence shall have all powers to formulate guidelines for the THSTI PhD program within the JNU regulations as detailed in their PhD ordinance. The broad contours of the THSTI PhD program are defined below.

Admission to THSTI-JNU PhD program will be announced through national newspapers. Admissions may be made during the summer as well as winter semester depending upon the availability of studentships and infrastructure logistics. A maximum of 30 students will be admitted in one academic year through a written test followed by an interview.

Candidates must have Master's degree in any branch of life science, MVSc, MTech, MPharm, or a medical degree (MBBS or BDS) from a recognized university. Except for medically qualified candidates, all others must hold the junior research fellowship awarded by CSIR, UGC, ICMR, or DBT. Shortlisted candidates will be interviewed and the final selection will be made based on their performance in the written test and/or interview. Medically qualified candidates without the junior research fellowship will have to appear in a national level examination. The final selection will be made based on their performance in the written test and/or interview.

Students recommended for admission to the PhD program and holding fellowship from any of the above agencies will be required to utilize their own fellowship. Medically qualified candidates selected though the admission test will be awarded THSTI fellowship as per the Govt. of India rules.

THSTI Executive Director will constitute a PhD admission committee with responsibility to conduct the test and hold interviews. The interview committee to recommend the students for admission to the PhD program will have at least one faculty member from JNU.

Academic program

The selected students will undergo one semester of pre-PhD course work. Those having successfully completed the pre-PhD course requirement will be recommended by the AC to JNU for registration and allowed to continue research towards their PhD thesis.

A doctoral committee (DC) for each of the students will be constituted by the supervisor with approval from THSTI Dean. The DC will meet at least once every year to review the progress of the student and make appropriate suggestions and recommendations on continuation of studentship and fellowship and its upgrade. The DC will also review the work of the student and approve it to be prepared as PhD thesis. This will be followed by the submission of the thesis synopsis by the student to be reviewed and approved by the AC before thesis could be submitted to JNU for its evaluation. Once a favorable thesis examination report is made available from JNU, thesis defense shall be conducted at THSTI, report of which shall be submitted to JNU. Following the successful thesis defense, JNU will take appropriate action to award the doctoral degree to the candidate.

Pre-PhD Registration Course

The students admitted to THSTI PhD program will be required to undertake courses to earn 14 credits to be eligible to undertake thesis research work. The courses offered over the two semesters are:

SEMESTER-I		
Biomedical Research : Concepts and Methods	THS-1	3 credits
Clinical Research Methodology	THS-2	3 credits
Research Internship	THS-3	2 credits
Health Policy and Decision Analysis in Health	THS-4	2 credits
SEMESTER-II		
Infectious Disease Biology	THS-5	2 credits
Infectious Disease Epidemiology	THS-6	2 credits
Immunology and Immunotechnology	THS-7	2 credits
Special Topics in Epidemiology	THS-8	3 credits
Essentials of Clinical Trials	THS-9	3 credits
Essentials of Regulatory Trials	THS-10	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 on a scale of 10 will be required for successful completion of Pre-PhD registration course program. Students who fail to obtain a CGPA of 6.5 or fail to achieve a minimum 'B' grade in a particular course will be offered another opportunity to appear for a supplementary examination 15 days after the declaration of final results. 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.

Other educational programs

Masters of Science for Physicians (in collaboration with RCB)

Masters in Medical Science program is being developed as a transitional program that gives medical background persons, broad, interdisciplinary exposure to areas relevant to Biomedical research both clinical and/ or translational. This will be an important flagship program of RCB in collaboration with THSTI. The relevant expert group committees have been created and the details of the program are being discussed.