

(An Autonomous Institute of the Department of Biotechnology, Govt. of India)

NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurugram Expressway,

P.O. Box No. 04, Faridabad - 121001

ADMISSION TO MASTER OF SCIENCE (M.Sc.) IN CLINICAL RESEARCH (SPECIALISATION IN CLINICAL TRIALS)

A) Translational Health Science and Technology Institute (THSTI) is a part of the inter-disciplinary Biotech Science Cluster at Faridabad in the National Capital Region. THSTI is a dynamic and interactive organization with a mission to conduct innovative translational research across disciplines and professions to accelerate the development of concepts into products to improve human health.

B) Applications are invited for admission to <u>Master of Science (M.Sc.) in Clinical Research (Specialisation in</u> Clinical Trials) for the academic session 2022-2024.

C) Course details:

- (i) This is a two-year, post-graduate degree course coordinated by THSTI. The degree will be awarded by the Regional Centre for Biotechnology (RCB), recognized as an institution of National Importance by the Parliament of India, established by the Department of Biotechnology, Government of India with regional and global partnerships synergizing with the programs of UNESCO as a Category II Centre
- (ii) The course curriculum is enclosed as Annexure-A
- (iii) The course will commence on **September 26, 2022**
- (iv) Tuition fee: INR 25,000 per semester (there will be four semesters) For OBC/EWS, the fees will be Rs.18,750/- per semester and for SC/ST/PwBD candidates, the fees will be Rs.12,500/- per semester.

D) Facilities:

- i) Hostel accommodation with mess (payment, at actuals)
- ii) State-of-the-art campus with many recreational facilities
- iii) Visit to hospitals, industry, and clinical research/trials sites for hands on training.
- iv) Internship with academic institution, industry, regulatory agency and research organization, etc.
- v) Engagement in actual ongoing clinical trials of the institution during dissertation period for hands on training
- vi) Support for placements
- vii) Possibility of continuing with Ph.D. subject to fulfillment of the THSTI Ph.D. policy
- E) **Minimum eligibility criteria**: Graduation from a recognised university with a minimum of 50% marks in aggregate in any of the following:
 - i) Bachelor's degree in Allopathic Medicine (MBBS)
 - ii) Bachelor's degree in other fields of Medicine/Dentistry/Nursing/Veterinary Science (BHMS/BAMS/BDS/BSc Nursing/BVSc)
 - iii) Bachelor's degree in Pharmacy/Life Sciences/Statistics/Public Health (B Pharm/BSc/ B Tech)

Note: Candidates awaiting their graduation results can also apply. They will be considered subject to submission of their graduation result (mark list and at least the provisional degree certificate) on the day of the interview.

F) Filling up of seats:

- i) Number of seats: 15
- ii) Reservations: 27% seats for Other Backward Classes (OBC) (non-creamy layer), 15% seats for Scheduled Castes (SC), 7.5% seats for Scheduled Tribes (SC) (ST), 10% seats for Economically Weaker Sections (EWS), and 4% seats for the differently abled person (Person with Benchmark Disability, PwBD) are reserved for candidates belonging to these categories. SC/ ST/ OBC /EWS candidates are required to submit certificates in respect of their claims from authorized officers as notified by the Government for the purpose from time to time. The differently abled, (with a minimum of 40% disability) candidates are required to submit a certificate from authorized Medical Doctors/ Hospitals indicating the extent of physical disability.

G) Selection process:

- i) Written test will be followed by an interview.
- ii) Those candidates who score 60 percentile and above in the written test will only be called for the interview subject to the same being more than or equal to 40% marks.
- iii) The minimum qualifying marks to be scored in the interview will be 60% marks.
- iv) Relaxation upto 5% for OBC and 10% for SC/ST will be given, if required.
- v) Written test and interview will be held at THSTI, Faridabad, Haryana, India.
- vi) All instructions pertaining to syllabus, date, time, venue, etc. will be sent separately before the written test to the shortlisted candidates.
- H) Application process: The eligible and interested candidates will apply online at the Institute's website https://thsti.in/application/jobs.php Applications through any other mode will not be accepted.
 - i. Procedure for filling up online application:

Step 1 : Details of applicant

Step 2: Uploading of documents

Step 3: Payment of application fee

- The payment can be made by using Debit Card / Credit Card / Internet Banking / UPI.
- Once payment is made, no correction / modification is possible.
- > Candidates are requested to keep a copy of the provisional receipt for future reference.
- Fee once paid shall not be refunded under any circumstances.
- Details of fees to be paid are as shown below:

Note: SC/ST/Women/PwBD candidates are exempted from payment of application fees

- ii. Documents to be kept handy before filling up the online application: (all the documents except (a) should be in pdf format):
 - (a) A soft copy of your recent passport size photo and signature (jpeg/jpg/png format)
 - (b) Matriculation certificate (equivalent to 10th Standard) / Mark sheet
 - (c) Intermediate certificate (equivalent to 12th Standard) / Mark sheet
 - (d) Graduation degree certificate and Mark sheet
 - (e) Caste / Disability certificate (if applicable) in the format prescribed by the Govt. of India

Note: i) Candidates are required to keep a printout of the online application form by using the print button on the dashboard for future reference.

ii) Providing false/incorrect information in the application form or non-possession of essential

- qualification detected at any stage of the selection process will lead to disqualification of the candidate.
- iii) Incomplete applications will be rejected and no correspondence in this regard will be entertained.
- iv) In case of difficulty in filling up the online form, please send an e-mail to training.cdsa@thsti.res.in along with the screenshot of the error displayed (if any).

Other conditions:

- i) During the course, the student will not apply for any other course/post graduate program/ scholarship or appear for any examination or interview outside. If the student has applied for any of the above before applying for this program, she/he must give proper information to this institution.
- ii) Candidate must ensure that he/she fulfills all the eligibility criteria as stipulated in the advertisement. If it is found that he/she does not fulfill the stipulated criteria by misinterpretation or any other reason during the selection process, the candidature of the candidate will be cancelled. If the same is noticed after the admission, the candidate will be terminated following due process.
- iii) All future communications will only be through email.
- iv) All results/notifications will be published on our website and therefore the candidates are required to visit THSTI website regularly till the completion of the admission process.

J) Important dates:

Last date of online application	17 th August 2022	
Date of declaration of shortlisted candidates	25 th August 2022	
Date of written test/Interview	14 th September 2022/15 th September	
	2022	



COURSE CURRICULUM

Master of Science (M.Sc.) Program in Clinical Research

(Specialisation in Clinical Trials)

Course provider Clinical Development Services Agency, Translational Health Science & Technology Institute

Supporting institutions

Medical Research Council Clinical Trials Unit at University College London, United Kingdom; Christian Medical College, Vellore; Center for Health Research and Development - Society for Applied Studies, New Delhi; King Edward Memorial Hospital, Pune; Jagadguru Sri Shivarathreeshwara University, Mysuru

Master of Science (M.Sc.) in Clinical Research (Specialisation in Clinical Trials)

COURSE CURRICULUM

No.	Course title	Code	Credits*
		THS	
	Semester I		20
1.1	Principles and practice of clinical research	251	3
1.2	Drug discovery, drug development, and pre-clinical studies	252	2
1.3	Basics of epidemiology	253	2
1.4	Basics of clinical pharmacology	254	2
1.5	Introduction to biostatistics	255	2
1.6	Clinical research methodology	256	2
1.7	Ethical considerations	257	3
1.8	GxP (GMP, GLP, GCLP, GCP)	258	2
1.9	Intellectual property rights and patenting	259	2
	Semester II		20
2.1	Regulatory aspects of clinical trials	351	3
2.2	Clinical trial design and planning – Conventional and adaptive	352	3
2.3	Application of biostatistics to clinical trial design	353	3
2.4	Protocol development	354	3
2.5	Clinical trial set up and conduct	355	3
2.6	Clinical data management	356	3
2.7	Internship programme	357	2
	Semester III		20
3.1	Protecting patients and patient engagement	358	2
3.2	Pharmacovigilance and safety reporting	359	2
3.3	Quality management in clinical trials	360	2
3.4	Financial management	361	2
3.5	Statistical analysis in clinical studies	362	3
3.6	Reporting and reviewing clinical trials, closing a trial, dissemination of trial results	363	3
3.7	Pharmacoeconomics and health technology assessment	364	2
3.8	Bioavailability and bioequivalence studies, pharmacokinetic and	365	2
2.0	pharmacodynamic studies	200	2
3.9	Scientific communication	366	2
	Semester IV		
4.1	Project dissertation	367	40
	(spread over four semesters)		
	Total credits		100

^{*}One Credit = 12 Teaching Hours; One Credit = 06 Hands-on Sessions (sessions of 02 hours each)