

(An Autonomous Institute of the Department of Biotechnology, Govt. of India) <u>NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurugram Expressway, P.O. Box No. 04, Faridabad - 121001</u>

RECRUITMENT NOTICE NO. : THS/RN/16/2022

Dated 5th May 2022

RECRUITMENT FOR VARIOUS POSITIONS

- 1. Translational Health Science and Technology Institute (THSTI) is an autonomous Institute of the Department of Biotechnology, Ministry of Science and Technology, Govt. of India. The institute is an integral part of the interdisciplinary NCR Biotech Science Cluster located at Faridabad, and is designed as a dynamic, interactive organization with the mission to conduct innovative translational research and to develop research collaborations across disciplines and professions to translate concepts into products to improve human health.
- 2. THSTI has built several inter-institutional collaborations and connectivity with industry supported by well-trained teams of research and laboratory staff. This foundation has helped pursuit of thematic research programmes broadly categorized as, (a) Infectious diseases and Immunology (b) Maternal and child health, (c) Non communicable disease d) Multidisciplinary clinical and translational research. These are strengthened by the four core facilities viz. Small Animal Facility, Data Management Center, Biorepository and Bioassay Laboratory that serve as huge resources for the research programmes of THSTI, and also the National Capital Region Biotech Science Cluster and other academic and industrial partners.
- 3. This recruitment is to fill up the vacancies under the project entitled "A multi-country, multicentre, three-arm, parallel group, double-blind, placebo-controlled, randomized trial of two doses of antenatal corticosteroids for women with a high probability of birth in the late preterm period in hospitals in low-resource countries to improve newborn outcomes (ACTION-III Trial)"

Educational Qualification and Experience required for the post:

S.	Name of the Post/	Minimum Qualifications &	Desirable Qualification &
No.	No. of Post /	Experience	Experience/Job Responsibilities
	Maximum		
	Monthly		
	consolidated		
	emoluments/		
	Age Limit		
1.	Clinical Research	MD/DNB preferably in Obstetrics	The Clinical Research Coordinator (CRC)
	Coordinator	and Gynaecology / Pediatrics/	will be leading the study team and will be
		Community Medicine with atleast	primary point of contact for operational
	One post	one year of experience after	aspects of implementation of the clinical
		completing MD/DNB. OR	trial activities from study start-up through database lock, ensuring compliance with
	Rs. 1,30,000/-	Diploma in Obstetrics and	GCP and applicable guidance. He/ she will
		Gynaecology /Child Health/	be the primary link between study
	45 years	Pediatrics with atleast two years of	coordination unit and study investigators.
		post-degree experience.	The CRC will have an oversight
		OR	responsibility for activities undertaken at

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 MBBS with atleast four years work experience after completing internship, preferably in the field of Obstetrics and Gynaecology/ Pediatrics OR MBBS plus MPH with atleast two years of work experience in clinical research after completing MPH. Desirable: 2 years of work experience in a clinical trial or a public health project. Understanding of GCP, regulations and guidelines Demonstrated ability to develop and implement monitoring plans, SOPs Computer skills including proficiency in use of Microsoft Office applications Ability to build effective project teams, ability to motivate others, delegation, drive and timely/ quality decision making Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards Effective communication skills, the provision of timely and accurate information to stakeholders Good organizational behavior and problem-solving skills Effective time management skills and ability to manage competing priorities 	 hospital site. He/she will be responsible for: Providing input into and/or developing study related material such as clinical operations plan, SOPS, CRF completion guidelines, informed consent, study logs/forms and other study related documents: Supporting the submissions for relevant government / ethics approvals; Developing training module and planning the initial and retraining sessions for the research study staff along with the site CROs (called clinical research officers) Contribute through operational inputs in protocol and study budget related decisions; Structuring and supervising compliance for the study management plans; Ensuring compliance with the project requirements and cascading the issues/ updates to the relevant stakeholders; Supervising the site preparation, study implementation at site and ongoing study and QC activities; Reviewing protocol deviations and loss to follow up to ensure quality data is delivered; Communicating with site supervisor and site investigator for tracking patient recruitment and progress to study timelines; maintaining and reporting metrics for clinical site performance Providing input and support to maintain appropriate documentation for adverse event safety monitoring, and collaborating in submission of safety reports to sponsor, Ethics Committees and other applicable authorities; Liasoning with the QM team to ensure good quality of study data ; Providing support to site team to prepare for clinical audits and to respond to audit findings conducted by internal QA and external agencies; Supervising the data management progress with data manager and the

			 DM team; Work with coordinating PI to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding, or timelines; Keeping stakeholders informed on study progress, risks and accomplishments. Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards
2.	Senior Clinical Research Officer Five posts Rs. 1,25,000/- 45 years	 MD/DNB or equivalent degree in Obstetrics and Gynaecology from MCI recognised University. Desirable: 2 years of work experience in a clinical trial or a public health project. Conversant with Good Clinical Practice Demonstrated ability to develop and implement monitoring plans, SOPs Computer skills including proficiency in use of Microsoft Office applications Ability to build effective project teams, ability to motivate others, delegation, drive and timely/ quality decision making Good organizational behavior and problem-solving skills Effective time management skills and ability to manage competing priorities. 	 The selected candidates will be responsible for oversight of activities related to screening, enrolment and administration of intervention and outcome assessment of mother and ensuring that the study is conducted in accordance with study protocol, standard operating procedures, good clinical practice, and applicable guidelines. It will involve coordination between investigators, project conduct team, data management team and monitoring team; tracking progress of project with updates; safety reporting within the prescribed timelines; monitoring deliverables; and ensuring adherence to regulatory requirements. She/ He will be responsible for: Performing the dating USGs Oversight and coordination of screening, enrolment and IP administration. Oversight of monitoring of mothers till discharge Safety reporting for adverse events; preparing the SAEs reports to be shared with all stakeholders in a timely manner Review and verification of completed CRFs in a timely manner, before they are transmitted to data management team for entry

		 Timely resolution of queries in data collected. Supervising the study processes to ensure compliance to SOPs, protocol, national regulations; supervision of process of taking written informed consent; Coordinating the smooth flow of data from collection to data entry in electronic platform Reviewing participant recruitment, protocol deviations, loss to follow up for hospital site performance; Responsible for intervention at sitestock, storage at appropriate temperature Responsible for equipment related to maternal assessments Training of research assistants and field workers for maternal data collection, outcome assessments, follow-ups, CRF completion Liaising with the QM team to ensure good quality of study data Any other work assigned by Pl
Clinical Research Officer Five posts Rs. 1,00,000/- 45 years	MD/DNB or equivalent degree in Pediatrics from MCI recognised University. OR DCH or equivalent degree in Pediatrics from MCI recognised University. OR MBBS from MCI recognized University with at least three years of work experience after completing internship, preferably in the field of Pediatrics OR MBBS from MCI recognized University and MPH with at least one year of post qualification work experience preferably in the field of Pediatrics. OR BDS/ BAMS/ BHMS/ BPT or equivalent degree from MCI	 The selected candidates will be responsible for oversight of activities related to outcome assessment of newborn, and ensuring that the study is conducted in accordance with study protocol, standard operating procedures, good clinical practice, and applicable guidelines It will involve coordination between investigators, project conduct team, data management team and monitoring team; tracking progress of project with updates; safety reporting within the prescribed timelines; monitoring deliverables; and ensuring adherence to regulatory requirements. She/ He will be responsible for: Oversight and coordination of outcome assessment in newborns. Oversight of monitoring of newborns till discharge

		recognised University and MPH with at least three years of post qualification work experience preferably in the field of Pediatrics. OR BDS/ BAMS/ BHMS/ BPT or equivalent degree from MCI recognised University with at least five years of post-qualification work experience after completing internship, preferably in the field of Pediatrics. Desirable: • 2 years of work experience in a clinical trial or a public health project or a MPH degree • Conversant with Good Clinical Practice • Demonstrated ability to develop and implement monitoring plans, SOPs • Computer skills including proficiency in use of Microsoft Office applications • Ability to build effective project teams, ability to motivate others, delegation, drive and timely/ quality decision making • Good organizational behavior and problem-solving skills • Effective time management skills and ability to manage competing priorities.	 Safety reporting for adverse events in newborns; preparing the SAEs reports to be shared with all stakeholders in a timely manner Review and verification of completed CRFs in a timely manner, before they are transmitted to data management team for entry Timely resolution of queries in data collected. Supervising the study processes to ensure compliance to SOPs, protocol, national regulations; supervision of process of assessing respiratory support in newborn, anthropometry, hypoglycemia, sepsis, etc Ensuring timely follow-up visits of all newborns till end of study; liaising with project manager for this activity Coordinating the smooth flow of data from collection to data entry in electronic platform Reviewing data queries, protocol deviations, loss to follow up for hospital site performance; Responsible for equipment related to newborn assessments at site Liaising with the QM team to ensure good quality of study data Training of research assistants and field workers for newborn data collection, outcome assessments, follow-ups, CRF completion Any other work assigned by PI
4.	Project Manager One post Rs. 65,000/- 45 years	Essential Qualification and Experience: Master's degree in Life Sciences/Pharmacy/ Public health with at least two years of post- qualification work experience in clinical project management and/or clinical trial or public health project management. OR	The selected candidate will be responsible for project management of one site for a large randomized controlled trial. It will involve coordination between investigators, project conduct team, data management team and monitoring team; liaising with the funding agency; tracking progress of project with updates; monitoring deliverables; and ensuring adherence to regulatory requirements.

Post graduate degree in a health	Ho/Showill borosponsible for
Post graduate degree in a health- related discipline/ health administration with at least two years of post qualification work experience in clinical project management and/or clinical trial or public health project management. OR Graduate in any discipline with at least seven years of post qualification work experience in clinical project management and/or clinical trial or public health project management. Essential: • Prior experience in working in a similar role within a renowned research/academic setting • Demonstrated ability to understand, explain and communicate and manage project conduct (track trial progress, quality, and risk management) using standard tools and templates • Computer skills including proficiency in use of Microsoft Office, Ms-Word, Excel, Power- point applications Desirable: • Demonstrable application of project management concepts • Effective time management skills and ability to manage competing priorities. • Good knowledge of Excel for office accounting and budgeting • Good organizational behavior and problem-solving skills • Ability to establish and maintain effective working relationships with co-workers, research officers, investigators • Familiarity with the regulatory frameworks of biomedical research.	 He/ She will be responsible for : Implementing, maintaining and developing efficient and effective administrative systems Assisting in compilation and preparation of briefing and presentation materials, speeches, background information and documentation for meetings Drafting of regular interval-based reports for investigators and other stakeholders Following up on deadlines, commitments made, actions taken and coordinate collection and submission of reports Maintaining filing system ensuring safekeeping of confidential materials. Preparation of all necessary documentation, implementation of follow-up actions Responsible for all logs (calibration, equipment maintenance, training, etc), registers (all enrolments, scheduled follow up registers), documents and site file (updated protocol, informed consent document, eCRF and paper CRFs, all relevant permissions) Providing support for efficient functioning of the Project Team Ordering and checking resources and purchases for the team Primary liaison to the Procurement Department at THSTI for equipment order placement, processing invoices when received Management of office stationery supplies, including maintenance of office assets and stationery Handling requests of travel and logistics arrangements for the team Providing admin support to conferences, workshops and project related field visits Assisting in the coordination and delivery of workshops Processing requests for identity cards and other documents for research staff. Supervise filed technicians

			The project manager will be based at Safdarjung hospital in Delhi.
5.	Data Manager One post Rs. 65,000/- 45 years	Essential Qualifications and Experience: Post graduate degree in Computer Application/ Computer Science/ Data Science from a recognized University with atleast two years of post qualification work experience in clinical data management. OR Graduate degree in Computer Science/ Computer Application from a recognized University with atleast five years of post qualification work experience in clinical data management. OR Graduate degree in any discipline with computer diploma from a recognized Institute/University with atleast seven years of post qualication work experience in clinical data management. Essential: • Experience in Clinical Data Management, Database Administration and Software Development • Demonstrated experience in preparation of Clinical Study Data Management documents • Demonstrated experience in software validation and documentation Desirable : • Working knowledge of clinical database development, testing and validation methodologies and software documentation. • Sound IT skills • Knowledge of server & hardware maintenance	 The selected candidate will be responsible for taking lead in data management for the mentioned randomized controlled trial, timely delivery of key tasks, while maintaining high quality standards. Mentoring and development of the data management team is a key outcome area for this role. The Data Manager will serve as a point of contact for the sponsor. He/She will work closely with the central data management team of THSTI and WHO and will be responsible for: Site clinical data management in coordination with the central data management team at THSTI & WHO Developing and implementing data management standards and procedures; especially in terms of data protection and data security, data back up plan Deploying and maintenance of study database. Review and finalize the data management plan and working practice documents. Contribute to development of edit checks for the trial Develop tools to track screened and enrolled participants Overall data management, query management, data cleaning. Timely report generation, to track study progress, identify triggers of non-compliance Escalating triggers on variables that are critical to quality. Supervise data entry operators Any other work as assigned by Pl
6.	Project Assistant (IT)	Graduate degree in Computer Science/Information Technology	Good understanding of IT infrastructure stack
	One post	/Computer Application or equivalent with five years of post- qualification experience in the	Good understanding of Network architecture and related security risks
	Rs. 45,000/-	relevant field.	

	35 years	Desirable experience and skills: • CCNA or higher • Hands-on experience with monitoring, network diagnostic and network analytics tools	 Maintaining & troubleshooting computer networks including VPN, routers and physical hardware Configuration of Firewall. Secures network system by establishing and enforcing policies and defining and monitoring access. Traffic inspection Configuration and maintenance of Servers, IPs Can work on VMware platforms Configuring and installing various network devices and services (e.g., routers, switches, firewalls, load balancers, VPN, QoS) Monitor network activity and configure network systems using complex computer software, DHCP, DNS, Expertise in LINUX Server Administration
7.	Project Assistant One post	Essential Qualification and Experience: Post graduate degree in a health-	The selected candidate will be responsible for providing support to project office operations performing a
	Rs. 45,000/-	related discipline with at least one year of post qualification relevant/	variety of standard administrative duties including typing of official documents
	1\3. 43,000/-	administrative experience in government organization/	ensuring high quality and accuracy of work.
	35 years	organization of repute. OR Graduate in any discipline with at least three years of post qualification relevant/ administrative experience in government organization/ organization of repute Essential: • Good English communication skills • Demonstrated ability to understand, explain and communicate and manage project using standard tools and templates • Computer skills including proficiency in use of Microsoft Office, Ms-Word, Excel, Power- point applications Desirable: • Proficiency in typing • Should be able to handle word processor and conversant with secretarial practice Effective	 administrative systems Providing admin support to conferences, workshops and project related field visits Assisting in compilation and preparation of briefing and presentation materials, speeches, background information and documentation for meetings Arranging for travel and hotel reservations; preparing travel authorizations, Processing requests for visas, identity cards and other documents for research staff.

		time management skills and ability to manage competing priorities. Good knowledge of Excel for office accounting and budgeting Interpersonal skills and ability to work effectively in a team	 extension, salaries; procurement of equipment and consumables for site Developing a system to ensure timely delivery of supplies to site Primary liaison to the Procurement Department for equipment order placement process invoices when received Handling requests of travel and logistics arrangements for the team Arranging vehicle transportation, regular vehicle maintenance and insurance; Management of office stationery supplies, including maintenance of office assets and stationery, distribution of stationery as required by staff and keeping a log of distribution Maintaining filing system ensuring safekeeping of essential documents for the trial; Follow up on deadlines, commitments made, actions taken
8.	Research Assistant Fifteen posts Rs. 32,000/- 35 years	Standard 12 th and Diploma in Nursing & Midwifery (GNM) or equivalent and registered nurse or ANM OR BSc (Nursing) OR Nursing "A" Certificate with 3 years' experience in hospital OR Nursing Assistant Class III & above form the Armed Forces. Desirable: • 2 years' work experience in Obstetrics or Midwifery or Dept of Neonatology or Nursery • Computer skills including proficiency in use of Microsoft Office applications • Ability to establish and maintain effective working relationships with co-workers, managers, investigators • Good understanding of needs for project and job responsibilities.	 The project assistant will be based at THSTI The research assistants (RAs) will perform shift duties to provide cover for the trial round the clock (24 X 7). Different teams of RAs will be formed for screening and enrollment, administration of intervention and monitoring, outcome assessment in newborns and mothers. The selected candidates will be deployed in one of the teams on a rotating basis and will be responsible for: Pre-screening of all women reporting to the GRR/ emergency/ admitted in hospital for child birth in the late preterm period Taking written informed consent Screening the pregnant women for eligibility for participation in the study Assigning the correct intervention to a newly enrolled woman Administering the assigned intervention to the enrolled woman as per protocol;

	Effective communication skills to provide timely and appropriate information to study participants	 Completing the case report forms (CRF); Maintaining laboratory records Scheduling the follow up visits of the baby born to enrolled mother Making reminder calls to the parent (s)/ caregiver of infant for a scheduled follow up visit In case an enrolled infant has missed a scheduled follow up visit-informing the CRO for corrective action To carry out orders as prescribed by resident doctors. Any other as assigned by PI. The research assistants will be based at Safdarjung hospital in Delhi
9. Data En Operato Two pos Rs. 30,00 30 years	r Experience: Graduate degree in Compute Science/ Computer application from a recognized University with atleast two years of pos	responsible for data entry, query management He/ She will work closely with the data manager and will be responsible for: • Accurate transcription of data from paper CRF to the electronic platform in a timely manner • Query management • Tracking progress of study; generating update reports • Providing support in preparing presentations, • Providing support to project management team in typing of official documents. • Providing support during workshops and project related field visits. • Assisting in compilation and preparation of briefing and presentation materials, background information and documentation for meetings. • Any other work as assigned by Pl The data entry operators will be based at Safdarjung hospital in Delhi

		Ability to establish and maintain effective working relationships with co-workers, managers, investigators	
F	Field Worker Four posts Rs. 20,000/- 50 years	Standard 10 with minimum six years' of post qualification work experience in clinical trials/ health related research projects. OR Standard 12 with minimum four years' of post qualification experience in clinical trials/ health related research projects. OR Degree/ Diploma in MLT with minimum two years' of post qualification experience in clinical trials/ health related research projects. OR Degree/ Diploma in clinical research. Desirable: • Work experience in community trials/ as clinical field workers/ in the maternal and child health domain • Basic business computer skills (MS Word, Excel, e-mail) • Well versed in recording the data • Effective communication skills	 The field worker may be asked to perform shift duties to provide extended cover for the trial. The selected candidates will be responsible for: Daily calibration of equipment at site; maintaining equipment log, calibration logs, ensuring smooth functioning of equipment at site Transportation of investigational product (IP) at site and central facility at THSTI, prepare logs and liaising with the Project Manager. Inventory management (at site) Transportation of laboratory samples to hospital site lab/ any laboratory in the close vicinity of the hospital Collecting reports of routine laboratory tests performed for enrolled participant or her newborn from the hospital lab or other laboratory Maintaining laboratory records Follow up of all enrolled mothers and their newborns; making home visits to the enrolled participants house for post discharge data collection if the need arises Making reminder calls to the enrolled participant for scheduled follow up visits Escorting the mother-newborn duo to their home at the time of discharge Ensuring cleanliness at site Assisting the project manager/ CRO/ research assistant/DM team in all study related activities at the site Assisting the project manager in maintaining all documentation at site-photocopying or scanning of documents if required Any other as assigned by PI/ co PI

► The tantative dates of written test/skill test/interivew: 27-31 May 2022

GENERAL TERMS & CONDITIONS:

- a) These are short-term positions and extension will be granted subject to satisfactory performance of the incumbents and tenure of the project for which they are selected. Those appointed to these positions will not have any claim for regularization of their employment.
- b) All educational, professional and technical qualification should be from a recognized Board/University.
- c) The experience requirement specified above shall be the experience acquired after obtaining the minimum educational qualifications specified for the post.
- d) Closing date of online application will be the CRUCIAL DATE for determining eligibility with regard to age, essential qualification etc.
- e) The age limit, qualification, experience and other requirements may be relaxed at the discretion of the competent authority, in case of candidates who are otherwise suitable. In case candidates are not found suitable for the posts notified, they can be offered lower post / lower emoluments on the recommendation of the Selection Committee.
- f) Age and other relaxations for direct recruits and departmental candidates: 1. By five years for candidates belonging to SC/ST communities. 2. By three years for candidates belonging to OBC communities. 3. For Persons with Benchmark Disabilities (PwBD) falling under the following categories : (i) UR ten years, ii) OBC 13 years (iii) SC/ST 15 4. Age is relaxable for Central Government servants up to five years in accordance with the instructions or orders issued by the Central Government, from time-to-time. 5. There is no upper age limit for the Institute employees who are treated as departmental candidates.
- g) All results will be published on our website and all future communications will be only through email
- h) In case a large number of applications are received, screening will be done to limit the number of candidates to those possessing higher/relevant qualification and experience.
- i) With regard to any provisions not covered in this notification, the bye laws of THSTI / Govt. of India rules / guidelines shall prevail.
- j) Canvassing wrong in any form will be a disqualification

HOW TO APPLY:

- 1. <u>Documents to be kept handy before filling up the online application:</u> (all the documents except (i) should be in pdf format) :
 - i) A soft copy of your passport size photo and signature. (jpeg/jpg/png format)
 - ii) A comprehensive CV containing details of qualification, positions held, professional experience / distinctions etc.
 - iii) Matriculation certificate (equivalent to 10th Standard) / Mark sheet
 - iv) Intermediate certificate (equivalent to 12th Standard) / Mark sheet
 - v) Graduation/Diploma degree certificate / Mark sheet (if applicable)
 - vi) Post-Graduation degree certificate & Mark sheet (if applicable)
 - vii) PhD degree/certificate (if applicable)
- viii) Relevant experience certificates (if applicable)

- ix) Caste / Disability certificate in the format prescribed by the Govt. of India, if applicable
- 2. Procedure for filling up online application:
 - i) The eligible and interested candidates may apply online at the Institute's website www.thsti.res.in/career. Applications through any other mode will not be accepted.
- ii) The following will be the step wise procedure-
 - A) Step 1 : Details of applicant
 - B) Step 2 : Uploading of documents
 - C) 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 forfuture reference.
 - > Fee once paid shall not be refunded under any circumstances.
 - > Details of fees to be paid are as shown below:

S. No	Applying on direct recruitment	Application fee amount
1.	Unreserved, OBC & EWS candidates	Rs 236/-
2.	SC/ST/Women/PwBD	Rs 118/-

D) Step 4 : Submission of application form

- iii) On successful submission of application, an auto-generated email containing the reference number will be sent to the email address provided. Please keep a note of the reference number for future correspondence.
- iv) Candidates are required to keep a printout of the online application form by using the print button on the dashboard for future reference.
- v) Candidates must ensure that he / she fulfils all the eligibility criteria as stipulated in the advertisement. If it is found that he / she does not fulfil the stipulated criteria during the recruitment process, the candidature of the candidate will be cancelled. If the same is noticed after the appointment, the candidate will be terminated following due process.
- vi) Incomplete applications shall be summarily rejected and no correspondence in this regard shall be entertained.
- vii) In case of difficulty in filling up the online form, please send e-mail to personnel@thsti.res.in along with the screenshot of the error displayed (if any).

"Government strives to have a work force which reflects gender balance and women candidates are encouraged to apply"

> (M.V.Santo) Head-Administration