ट्रांसलेशनल स्वास्थ्य विज्ञान
एवं प्रौद्योगिकी संस्थान
TRANSLATIONAL HEALTH SCIENCE
AND TECHNOLOGY INSTITUTE

(An Autonomous Institute of the Department of Biotechnology, Govt. of India)
496, Udyog Vihar Phase III, Gurgaon – 122 016

**Rolling Recruitment Notice No: THS / RN / 23 /2013**

**Recruitment of Clinical and Technical Staff**

a) Translational Health Science and Technology Institute (THSTI) is an autonomous Institute of the Department of Biotechnology under the Ministry of Science and Technology, Govt. of India. THSTI developed as a part of the interdisciplinary NCR Biotech Science Cluster to be located at Faridabad, in the National Capital Region. THSTI is designed to be a dynamic, interactive organization with a mission to conduct innovative translational research and to develop research collaborations across disciplines and professions to translate concepts into tangible products to improve human health. Permanent laboratories of the centre will come up in Faridabad within one year. The interim laboratories of the centre are functioning from Gurgaon in Haryana.

b) THSTI has set up niche centres for research in areas relevant to planned translational work. They are: Vaccine and Infectious Disease Research Centre (VIDRC), Pediatric Biology Center (PBC), Centre for Biodesign (CBD), Drug Discovery Research Centre (DDRC), Centre of Human Microbial Ecology (CHME) and Policy Centre for Biomedical Research (PCBR). Clinical Development Service Agency (CDSA) and the National Biodesign Alliance (NBA) are THSTI's extramural centres.

c) This advertisement is to fill up vacancies in "**Inter-institutional program on maternal and infant sciences**: ***A translational approach to studying preterm birth" -*** This inter-institutional program on maternal and infant sciences is a multidisciplinary research effort to predict & diagnose Preterm Birth (PTB) by increasing the understanding of the underlying pathophysiological mechanisms, which would facilitate use of existing or novel therapeutic agents & appropriate timing of clinical intervention.

d) The aim is to set up a hospital-based cohort of pregnant women starting from the first trimester, each of whom will be followed up until delivery. The first set of goals and objectives will be to use a cross disciplinary approach to understand the complex syndrome of PTB. The data collected in the current study will be analyzed in an integrative manner in generating new knowledge about the possible mechanisms and etiology of PTB.

e) The following are the vacancies under this programme. Candidates selected to fill up the vacancies under this programme will be posted either at clinical sites (General Hospital Gurgaon or Safdarjang Hospital) or at THSTI.

| S. No | Name of the position (no. of positions) / Monthly consolidated emoluments /Age limit / Type of position | Qualification & Experience | Job Description |
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| 1 | **Clinical Co-ordinator (1)**<br><br>Rs 80,000/-<br><br>45 years<br><br>Study based research position | MBBS from an accredited Indian University + 8 years experience after completing internship<br>Or<br>MD + 5 years experience<br>Or<br>MBBS from an accredited Indian University + MPH + 6 years experience.<br>**Desired**: 3 years experience in clinical research | Overall coordination with various collaborating clinical sites, training of staff at all levels, preparation and fulfillment of SOPs, quality control, liasoning between clinical sites and study investigators. |
| 2 | **Senior Resident (Obstetrics & Gynaecology) - (1)**<br><br>Rs. 70,000/-<br><br>40 years<br><br>Clinical Position | MD/DNB/DGO in Obstetrics & Gynaecology from an accredited Indian University.<br>Or<br>MBBS with atleast 2 yr. out of 3 yrs. of work experience in a field of interest i.e. (Obst & Gynae.) | • Conducting outpatient clinics in obstetrics & gynaecology for an urban and peri-urban population (includes outpatient preventive & antenatal care as per national norms),<br>• Conduct deliveries – normal, instrument assisted and caesarean section deliveries and postpartum care,<br>• Care of women admitted to a district hospital in Obstetrics & Gynaecology wards,<br>• Serve as the obstetrician for round the clock cover of patients admitted and those brought to the emergency services at the hospital,<br>• Liaison with senior Obstetric staff at the hospital to take and follow decisions regarding care of patients. |
| 3 | **Research Officer (1)**<br><br>Rs. 60,000/-<br><br>45 years<br><br>Study based research position | MBBS from an accredited Indian University + 3 years experience after completing internship<br>Or<br>MD / DNB in Obstetrics & Gynecology or Pediatrics<br>**Desired:** Experience in Obstetrics or Pediatrics clinical research for 1 year | The candidates will be responsible for the overall coordination of interventional and observational clinical or population studies that are conducted by THSTI at its collaborative clinical sites. The job responsibility includes training and supervision of research staff, supervision of data collection, data transfer and data analysis. It will also include organization and management of the study sites.<br><br>Preference will be given to candidates who are interested in enhancing their clinical research abilities by working in these research projects. There will be opportunities to enroll in 'learn while you work' short and longer term training |

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| | | | programs during the period of their employment. |
| 4 | **Study Nurse (6)**<br><br>Rs. 25,000/-<br><br>30 years<br><br>Study based research position | XII Standard and Diploma in Nursing & Midwifery (3 years course) plus Registration as "A" Grade Nurse<br>Or<br>BSc (Nursing)<br>Or<br>Nursing Assistant Class III & above from the Armed Forces.<br>**Desired:** Experience in Obstetrics or Midwifery or Pediatrics | Screening, enrolment and assessment of pregnant women, obtaining informed consent, data collection and sample collection from the pregnant women, cord blood collection. |
| 5 | **Clinical Data Entry Operator (2)**<br><br>Rs 25,000/-<br><br>30 years<br><br>Study based research position | Graduation in any discipline with 2 years experience as clinical data entry operator<br>Skills:<br>Basic computer skills<br>Good interpersonal skills<br>Good written and spoken English | • Receiving CRFs from clinical operations team<br>• Maintain accountability of received CRF pages<br>• Performing accurate data entry into the database<br>• Assist DM in designing the database<br>• Assist DM in raising queries<br>• Assist DM in resolution of queries<br>• Assist DM in CDM related documentation<br>Any other work given by DM |
| 6 | **Technician II (Clinical/Field) (3)**<br><br>Rs. 16,219/-<br><br>35 years<br><br>Study based research position | Class 10 with 3 years relevant work experience<br>Or<br>Class 12 with 1 year relevant work experience<br>Or<br>Diploma in MLT<br>**Desired:** Experience in in a laboratory / clinical field work | Handling samples, small equipment at THSTI and the clinical sites. Preparing samples at the clinical site & PBC for biochemical analyses. Home visits to collect study health information on case recording forms. |
| 7 | **Research Fellow (2)**<br><br>Rs. 20,800/-<br><br>26 years<br><br>Study based research position | MSc in Chemistry, Biochemistry or any other area of Life Sciences with relevant experience in the following fields: Basic techniques in molecular biology (genomic and plasmid DNA isolation, gel electrophoresis, polymerase chain reaction, spectrophotometry, column chromatography)<br><br>Maintenance of bacterial cells<br><br>MS Word, Excel, PowerPoint, Adobe Photoshop and other commonly used web-based bioinformatics tools. | Profiling and cataloguing human micro biome, identification and validation of microbial marker for early prediction of pregnancy outcomes |
| 8 | **Clinical Project Manager (1)**<br><br>Rs. 75,000/-<br><br>45 years | MBBS, BDS or Masters in Life science with 7 or more years of relevant work experience in clinical research projects, including 2 or more years of Clinical Project Management<br>**Skills:** | • Establishment of procedures to ensure adherence to trial protocols and administrative requirements<br>• Monitoring the trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate |

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| | Study based research position | • Leadership skills that include ability to build effective project teams, ability to motivate others, delegation, drive and timely/ quality decision making<br>• Personal qualities that include the ability to gain trust and confidence with stakeholders.<br>• Operational skills including focus and commitment to quality management and problem solving<br>• Influencing skills including negotiation and teamwork<br>• Effective communication skills that include the provision of timely and accurate information to stakeholders<br>• Proficient in English, strong written and oral communication skills<br>• Ability to develop and implement clinical research monitoring plans, SOPs, database concepts, and formats<br>• Understanding of the implications of GCP, regulations and guidelines<br>• Ability to remain flexible as projects and priorities change and work independently with minimal guidance as well as collaboratively within a team setting<br>• Computer literate (MS Word, e-mail, excel, internet)<br>• Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards<br>• Ability to develop technical reports and manuscripts | and rectify problems<br>• Act as the point of contact for all external and internal agencies<br>• Coordinate the preparation and publication of data, reports and information, ensuring that these meet legislative, contractual and ethical requirements<br>• Understand the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and coordinating any necessary audit processes<br>• Liaison with Steering Committee and DSMB with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements<br>• Provision of regular and ad hoc information, both written and verbal, to all the trial participants and sponsors, to include reports, updates, guidance, preformed commitments and, possibly, a Newsletter<br>• Work with the Investigators 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<br>• Assists Clinical management with the development, negotiation, and execution of the site contract, budget and payment plan<br>• Management of the trial budget(s) and maintenance of the accounts<br>• Development, approval, and distribution of study-related documents including Case Report Forms (CRF's), study protocols, study manuals, and other study tools to investigational sites and review committees<br>• Supervise the study start up activities, trial monitoring and reporting<br>• Manages distribution, collection and tracking of regulatory documentation to ensure compliance with regulatory and project requirements and audit readiness<br>• Support activities related to regulatory submissions and other reports as |

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| | | | required working closely with regulatory department<br>• Oversight for planning, preparing, and distributing materials for investigator and coordinator meetings, and for study related training<br>• Work with data management and other departments to track progress, milestones and the challenges<br>• Supervising and mentoring a team of monitors and project assistant<br>• Travel up to 50%, as assigned<br>Work with Clinical Portfolio Management team on their requirements as and when required |
| 9 | **Clinical Site Manager (1)**<br><br>Rs 65,000/-<br><br>45 years<br><br>Study Based Research Position | MBBS, BDS, BHMS, BAMS or Master's degree in life sciences with<br>3 or more years of relevant work experience in research projects, including 2 or more years of experience in research project site management<br>**Skills:**<br>• Leadership skills that include the ability to build effective site teams, ability to motivate others, delegation, drive and timely/quality decision making<br>• Personal qualities that include the ability to gain trust and confidence with stakeholders.<br>• Operational skills including focus, commitment to quality management and problem solving<br>• Influencing skills including negotiation and teamwork<br>• Effective communication skills that include the provision of timely and accurate information to stakeholders, proficient in English, strong written and oral communication skills<br>• Ability to develop and implement clinical site management plans, SOPs, database concepts, and formats<br>• Understanding of the implications of GCP, regulations and guidelines<br>• Ability to remain flexible as projects and priorities change and work independently with minimal guidance as well as collaboratively within a team setting<br>• Skills in computer statistical, technical, and database applications<br>• Familiarity with basic computer | • Overall efficient day-to-day management at investigator sites.<br>• Recruitment, retention, training, appraisal and supervision of study team members.<br>• Establishment of procedures to ensure adherence to trial protocols and administrative requirements<br>• Ensuring the timely recruitment of trial participants with secure randomization processes and subsequent efficient and effective data collection and management.<br>• Monitoring the study progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems.<br>• Management of the study budget(s) and maintenance of the accounts<br>• Act as the point of contact for site related aspects for external and internal agencies<br>• Co ordinate the preparation and publication of data, reports and information, ensuring that these meet legislative, contractual and ethical requirements<br>• Understand the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and coordinating any necessary audit processes<br>• Liaison with the Steering Committee and DSMB with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements |

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| | | software: word, e-mail, excel, internet<br>• Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards<br>Ability to develop technical reports and manuscripts | • Provision of regular and ad hoc information, both written and verbal, to all the trial participants and sponsors, to include reports, updates, guidance, commitments and, possibly, a Newsletter<br>• Work with the Investigators/Clinical Coordinator 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<br>• Planning and supporting the meetings and work of the various groups and bodies associated with the program<br>• Creation and maintenance of all trial files at clinical sites including referral sites<br>Assurance that personal and confidential information is restricted to those entitled to know |
| 10 | **Manager, Clinical Data Management (1)**<br><br>Rs 65,000/-<br><br>45 years<br><br>Study based research position | Bachelor's or master's degree in life science/computer science with 5 to 8 years of data management experience in the pharmaceutical or biotechnology industry, out of which 2-3 years of experience as DM Lead or Manager<br>**Skills:**<br>• Knowledge of GCDM Practices<br>• Proficient in Microsoft Office applications, Internet, software, E-mail<br>• Proficient with Clinical Data Management Systems (CDMS) and experience with Electronic Data Capture (EDC) systems<br>• Experience with SAS (Base, Stats, Macro, etc.)<br>• Experience with CDISC SDTM/CDASH | • Create and review (electronic) Case Report Forms per Protocol and annotated Case Report Forms<br>• Develop, review, and maintain a clinical database<br>• Develop, document and perform validation of database structure, data capture screens, code lists, edit checks, reports and other functions in EDC (e.g. User Acceptance Testing)<br>• Develop data transfer agreements and specifications with various vendors<br>• Write, review and maintain eCRF completion guidelines, data management plan (DMP), data validation plan (DVP, e.g. edit checks), and other DM related documentation<br>• Perform all aspects of DM process as related to processing and QC of the data<br>• Clean data for study close out and perform all database lock procedures<br>• Monitor study status (e.g. enrolment, CRFs, etc.) and provide status reports to the team<br>• Use standard conventions, tools, references and process in support of the coding of medical terms<br>• Ensures all DM procedures executed with a high attention to detail, accuracy and timelines<br>• Represent the DM function on project |

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| | | | teams<br>• Write and review DM SOPs in accordance with GCP and ICH guidelines, and develop associated training and competency testing<br>• Maintain CRFs and database standards<br>Work in conjunction with Clinical Operations, Clinical Research, and other operations to ensure accurate, efficient, and complete data collection |
| 11 | **Project Assistant**<br>**No. of Position (**2)<br><br>Rs 25,000/-<br>35 years<br><br>Study based research position | Bachelor's or Masters in any discipline with **a**t least with 3 years of relevant experience of providing support to Clinical Project.<br>**Skills**:<br>Good skills with Microsoft Office<br>Proven interpersonal skills and ability to work effectively in a team<br>Good written and spoken English<br>Administrative/ working knowledge. | • Assist with implementation of Pre-Term Birth Program<br>• Assist with setting up system and facilities as per project requirements e.g. equipment, supplies, etc.<br>• Create maintain and update files for all the purchases made for the project<br>• Take notes at meetings and distribute minutes of meeting timely<br>• Create, maintain and update project files<br>• Work with Support Group, for e.g. Purchase Dept. for purchases, Travel Dept. for project-related travel, Finance Dept. for payments, tender, or negotiations with vendors<br>• Support Team members (Research Associates, Managers, and others) on their requirements<br>As requested by Supervisor |

f) **GENERAL TERMS & CONDITIONS:**

i. All educational professional and technical qualification should be from a recognized board/university.

ii. The experience requirement specified shall be experience acquired after obtaining the minimum educational qualifications required for the post.

iii. Persons working in government or public sector undertaking should produce 'No Objection Certificate' at the time of Interview.

iv. The qualification, experience and other requirements for the post is relaxable at the discretion of the controlling authority, in case of candidates otherwise well qualified.

v. Interested candidates with relevant qualification and experience may send their CV along with passport size photograph and scanned copy of their certificates to pretermbirth@thsti.res.in. Applications received will be scrutinized on **6th January 2014** and thereafter 5th of every month.

Shortlisted candidates with relevant qualification and experience will be called for interview. **The first batch of shortlisted candidates will be called for interview on 20th January 2014.**

vi. Appointment will be made on a contract for a period of one year at a time with a possibility of extension based on satisfactory performance review. There will be an initial probation period of six months that may be extended at the discretion of the competent authority.

vii. All results will be published on our website and all future communications will be only through email.

viii. Canvassing in any form will lead to a disqualification.