INDIAN COUNCIL OF MEDICAL RESEARCH, NEW DELHI

Advt. No.: ITRC/ECD/1/2022 **Dated: 0 6 / 06/22**

ICMR intends to engage following Non-Institutional project human resource positions, purely on temporary contract basis for its short-term research projects, being undertaken at Division of Epidemiology and Communicable Diseases (ECD) (Unit-Tuberculosis, Leprosy andTribal Health), ICMR Hqrs, New Delhi.

Required qualifications and other details are given below.

Sr.No.	Project: Human Resource Position	No. of Positions	Essential Qualification	Consolidated Emoluments (per month)	Max age limit
1	**Project Scientist -V (Bio-Statistician/Data Scientist) (Non-Medical)** **Place of Work** ICMR Hqrs., New Delhi	**1(One) Unreserved**	**Essential:** • 1st Class Post Graduate Degree (Biostatistics /Statistics, M.Tech/MCA – Data Scientist/ Computer Science or equivalent) from reputed organization and 3 years of experience in data management preferably in clinical research/clinical trials. OR • 2nd Class Post Graduate Degree (Biostatistics / Statistics, M.Tech/MCA – Data Scientist/ Computer Science or equivalent) from reputed organization with Ph.D. in relevant subject with 3 years of relevant experience with published research papers.	Rs. 57,660/- Fixed Per month	Upper age limit upto 40 years. Age relaxation will be asper the Government of India/ICMR rules

	Job Requirement: a. To provide statistical support to all the studies/clinical trials Data management of all the clinical trials undertaken/coordinated by ITRC, ICMR. b. Planning data analysis and overseeing data clinical management on site c. Preparation of Statistical Analysis Plan of various projects. d. Preparation of Clinical Study Report in consultation with implementing institutions. e. To provide statistical inputs on sample size calculation, data analysis etc. on development of protocols by ITRC. f. Data Management in multicentric clinical trials/studies specially drug trials/vaccine trials. g. Data-cleaning, raising database queries, query resolution. h. Monitoring data of eCRF based studies i. Statistical analysis of the studies and preparation of report j. Support in Manuscript writing. k. The project may require travel outside Delhi. Any other work assigned by the competent authority.		**Desirable:** Knowledge of data management and SPSS. Ability to develop and advice on training programs. Experience of Data Management in multicentric clinical trials/studies specially drug trials/vaccine trials. . Experience in handling clinical trial data-base. . Experience in data-cleaning, raising database queries, query resolution. Experience in handling and monitoring eCRF based studies. Experience in statistical analysis and preparation of report.		

2	**Project Scientist Support-II (Medical Affairs and Clinical Development)** Place of duty: ICMRHqrs., Ansari Nagar, New Delhi. **Job Requirement:** a. Co-ordinate the activities of the India TB Research Consortium. b. Ensure that all processes contributing to the performance of a clinical trial are conducted properly as per the ITRC SOPs and consolidate the information pertaining to all the projects and activities undertaken for finishing the assigned tasks on time. c. Troubleshoot clinical trials and multi-centric projects. d. Prepare and assist in preparing annual reports and quality trending reports. e. Report the status of the quality levels of the staff, systems and production activities. f. To organize meetings, take care of logistics and administrative and financial approvals, draft letters for sending to various organizations and prepare the draft minutes of the meeting. g. Keep up to date with all quality and compliance issues. h. Process matters for sanction of the projects as recommended by expert groups of ITRC, take follow-up actions till release of budget. i. To review the progress reports of projects and take action for continuation. j. To work in team and undertake and share the responsibilities as and when required with other ITRC staff. k. Initiate and Manage new/ongoing Vaccine/drug trial/clinical research/bio-medical research projects.	**1(One) Unreserved**	**Essential**: • Post Graduate Degree (MD/MS/DNB) after MBBS with one year experience. **OR** • Postgraduate Diploma in Medical subjects after MBBS with two years' experience **OR** • MBBS degree with 4 years' experience in clinical research after MBBS **Desirable:** i. Master degree in the relevant subject (Community Medicine/ Preventive & Social Medicine/ Paediatrics/ Medicine/ Tropical Medicine/ Microbiology/Pharmacology/Community Health Administration/Health Administration/ Family Medicine/ Epidemiology/ Public Health) from a recognized university. ii. Thorough knowledge of New Drug and Clinical Trial Rules 2019 (Schedule Y), GCP, ICH guidelines and regulatory requirements for clinical trial conduct. iii. Additional Post-doctoral research/teaching experience in relevant subjects in recognized institute(s). Knowledge of Computer Applications or Business Intelligence tools /Data Management.	Rs. 72,325/- Fixed Per month	Upper age limit upto 40 years. Age relaxation will be asper the Government of India/ICMR rules

	l. Managing and maintaining databases for quality systems. m. Preparation of the protocols and budget for studies. n. Update the landscape documents in all thematic areas of TB. o. Able to prepare SOPs for trial conduct. p. Study feasibility, site feasibility, site identification (with CRPs) and site selection - Clinical studies and Observational Research. q. Regulatory submissions, in affiliates which are managed by Clinical Operations. r. Manage Site enrolment performance, and assist sites in recruitment planning. s. Develop site level risk plan for enrolment. t. The job may require travel to the trial sites and attending outstation meetings. u. Any other job assigned by PI or Program Officer				

Sr.No.	Project: Human Resource Position	No. of Positions	Essential Qualification	ConsolidatedEmoluments (per month)	Max age limit
1	**Project Scientist -II (Medical / Clinical Services) (Medical) – One post** **Place of Work** ICMR Hqrs., New Delhi **Job Requirement:** a. Monitor the clinical trial and Prepare strategy for site monitoring and timely completion of recruitment targets and follow -up visits b. Checking of resources and Site initiation c. Monitor vaccine trial, check all the source documents and completeness of data CRFs and ensuring timely completion of data entry in compliance with study protocol. d. Review SAE tracker and SAE document repository every 15 days e. Prepare a patient tracker and discuss with site PI to ensure compliance andminimize missing visits of subjects f. To match the tracker every week against recruitment target for each site andtake necessary actions accordingly g. Discussion with PI's and project staff for patient compliance h. Review of Ensure that all processes contributing to the performance of aclinical trial are conducted properly. i. Prepare and assist in preparing annual reports and quality trending reports. j. Prepare the site wise and consolidated site report regarding enrollment datavs. targets and share with Team lead/PO every week. k. Keep upto date with all quality and compliance issues and Report the statusof the quality levels of the staff, systems and production activities. l. Job may require all India travel to sites for monitoring, quality assurance andquality management for at least 15 days a month.	**1(One) Unreserved**	**Essential**: • Post Graduate Degree (MD/MS/DNB) after MBBS with one year experiencein clinical research **OR** • Postgraduate Diploma in Medical subjects after MBBS with two years' experience. **OR** • MBBS degree with 4 years of experience, preferably in clinical research/trialafter MBBS Degree. **Desirable:** i. Experience in conducting Vaccine/drug trial/clinical research /Clinical Management. ii. Able to prepare safety reports and ensure the timely management and reportingof AEs and SAEs by sites by supporting them iii. Experience in managing and maintaining databases for quality systems. iv. Able to prepare SOPs for trial conduct and write safety reports and SAE narratives. Knowledge of New Drug and Clinical Trial Rules 2019 (Schedule Y), GCP,ICH guidelines and other regulatory requirements for clinical trial conduct.	Rs. 72,325/- Fixed Per month	Upper age limit upto 40 years. Age relaxation will be asper the Government of India/ICMR rules

	Any other job assigned by the competent authority.				
Sr.No.	**Project: Human Resource Position**	**No. of Positions**	**Essential Qualification**	**ConsolidatedEmoluments (per month)**	**Max agelimit**
1	**Sr. Consultant (Project Management)** **Place of Work** ICMR Hqrs., New Delhi **Job Requirement:** Responsibilities: The activities of the Sr. Consultant would include but not limited to: a. Prepare the site selection and capacity building and strengthening plan and ensure that all the process of clinical studies are conducted properly by onsite or remote monitoring. b. Coordination of technical work with trial sites and Coordinating Unit in HQ. c. Troubleshoot of clinical trial at various study sites/centres. d. Prepare and assist in preparing over-all operational activities in trials at varioussites. e. Prepare and assist in preparing Annual Reports and quality trending reports. f. Perform proper pre-site initiation, Site-initiation, site-close out activities for all trials. g. Creation and Maintenance of Trial Master Files (TMF) and Site Master Files (SMF) for each trial site. Ensure proper documentation of all respective sections of TMF and SMF. h. Keep upto date with all quality and compliance issues. i. Perform risk-based monitoring. j. Any other job assigned by the competent authority. Job requires frequent all India travel to sites for coordination.	**1(One) Unreserved**	**Essential**: • Professional with M.D. or Ph.D. (Medical Pharmacology/Medical Microbiology/Public health/Life Sciences/Biotechnology/Biosciences) in relevantsubject from recognized Institution and published papers with 10 years of experience in clinical research/clinical trials with published papers. **OR** • Retired Government employees with requisite educational qualification of MD/Ph.D in Life Sciences with 10 years of experience in clinical research/clinical trial (related to TB research) drawing pay in pay band of Rs.15,600/-39100+grade pay of Rs.6600/-at the time of retirement **Desirable:** I. Experience in management and monitoring of regulatory Clinical Trials and Biomedical Research. II. Able to prepare SOPs, logs, protocols and other related documents for trial conduct. II. Knowledge of Regulatory Guidelines, New Drug and Clinical Trial Rules 2019 (Schedule Y), GCP, GCLP, ICH guidelines and other regulatory requirements for clinical trial conduct. . Experience in managing and maintaining databases for quality systems.	Rs. 1,00,000/- Fixed Per month	Upper age limits up to 70 years Age relaxation will be as per the Government of India/ICMR rules

2	**Consultant (Quality Assurance)** **Place of Work** ICMR Hqrs., New Delhi **Job Requirement:** The activities of the Consultant would include but not limited to: a. Design and develop the Quality Management System (QMS) and Work Instructions / Form & Logs which would consist designing of governing documents like Policies / General SOPs / Trial Specific SOPs / Trial Specific Plans / etc. b. Implement and sustain the QMS across all the sites to maintain compliance and uniformity across all clinical sites. c. Work along with the sponsor's / Site PIs to design the trial specific documents like SOPs, plans etc to ensure compliance to regulatory standards and maintain uniformity to establish QMS. d. Perform regular audits at the clinical trial sites to ensure compliance with the regulatory standards, study protocol & SOPs. e. Perform regular inspections of critical vendors at site to ensure compliance. f. Perform periodic system & process audits to ensure proper adherence of QMS across sites and centres. g. To prepare QA/QC Plan for the sites for all studies and participate in selection and management / Oversight of sites, CRO/vendors, develop vendor specifications, review vendor reports, budgets and metrics. h. Ensure periodic continual training programs for the clinical trial staff on important elements like GCP; Regulatory Guidelines; Study protocols etc. i. Face regulatory inspections. j. Keep upto date with all quality and compliance issues. k. The job may require frequent travel to all study sites for Quality maintenance Any other job assigned by the competent authority.	**1(One)** **Unreserved**	• **Essential:** Professionals with MD with 2 years' experience in quality assurance of clinical research/trial with published papers **OR** • or 1st Class Masters M. Tech. in Biotechnology/ M. Pharma/ M.Sc. in Pharmacology/ Clinical Research/Biochemistry/Chemistry/Biosciences with Ph.D. in relevant subject with 2 years' experience of Quality Assurance in Clinical Studies with published papers. i. **Desirable:** Experience in monitoring/Quality Assurance for conducting Vaccine/drugtrial/clinical research /Clinical Management. ii. Evaluating quality events, incidents, queries and complaints, handling compliance issues. iii. Experience in managing and maintaining databases for quality systems. Knowledge of regulatory New Drug and Clinical Trial Rules 2019 (Schedule Y), GCP, ICH guidelines and other regulatory requirements for clinical trial conduct.	Rs. 1,00,000/- Fixed Per month	Upper age limit upto 55 years Age relaxation will be as per the Government of India/ICMR rules

3	**Consultant (Clinical Research Associate)** **Place of Work** ICMR Hqrs., New Delhi **Job Requirement:** The activities of the Consultant would include but not limited to: a. To follow SOPs for a clinical trial. b. To monitor all aspects of study execution including assessing site, capacity building, processes development of various steps of clinical trial; follow study timelines and metrics. c. Job requires frequent all India travel to sites for monitoring, and site audit d. To participate in Site monitoring visits and oversee clinical monitoringactivities ensuring compliance with Good Clinical Practices. e. To prepare and/or review study related Standard Operating procedures andDocuments. f. To develop and manage study master files and site files. g. The job may require travel to the trial sites and attending out station meetings Any other job assigned by the competent authority.	**3 (Three)** **Unreserved**	**Essential:** • 1st Class Master Degree in Life sciences/Biotechnology/Bio-Medical sciences/M.Pharm or any equivalent degree from a recognized university with 4 years' experience or BAMS/BHMS/BDS/BV.Sc or any equivalent degree from a recognized university with 5 years' experience in Biotech/clinical research related to development of clinical research. Or • 2nd Class Master's Degree in Life sciences/Biotechnology or any equivalent degree + PhD degree in relevant subjects from a recognized university with 4 years' experience related to clinical research. **Desirable:** i. Ph.D. with 2 years post-Doctoral experience in biomedical subject particularlyin health research related areas. Working experience in Quality Control/Assurance. ii. Knowledge of computer applications or business intelligence tools/data management/data synthesis/Report writing, data mining, working on databases. Thorough knowledge of GCP, ICH guidelines and regulatory requirements for clinical trial conduct.	60,000/- Fixed Per month	Upper age limit for up to 55 years Age relaxation will be as per the Government of India/ICMR rules

4	**Consultant (Clinical Research Associate)** **Place of Work** ICMR Hqrs., New Delhi **Job Requirement:** The activities of the Consultant would include but not limited to: h. To follow SOPs for a clinical trial. i. To monitor all aspects of study execution including assessing site, capacity building, processes development of various steps of clinical trial; follow study timelines and metrics. j. Job requires frequent all India travel to sites for monitoring, and site audit k. To participate in Site monitoring visits and oversee clinical monitoringactivities ensuring compliance with Good Clinical Practices. l. To prepare and/or review study related Standard Operating procedures andDocuments. m. To develop and manage study master files and site files. n. The job may require travel to the trial sites and attending out station meetings Any other job assigned by the competent authority.	**3 (Three)** **Unreserved**	**Essential:** • 1st Class Master Degree in Life sciences/Biotechnology/Bio-Medical sciences/M.Pharm or any equivalent degree from a recognized university with 4 years' experience or BAMS/BHMS/BDS/BV.Sc or any equivalent degree from a recognized university with 5 years' experience in Biotech/clinical research related to development of clinical research. Or • 2nd Class Master's Degree in Life sciences/Biotechnology or any equivalent degree + PhD degree in relevant subjects from a recognized university with 4 years' experience related to clinical research. **Desirable:** iii. Ph.D. with 2 years post-Doctoral experience in biomedical subject particularlyin health research related areas. Working experience in Quality Control/Assurance. iv. Knowledge of computer applications or business intelligence tools/data management/data synthesis/Report writing, data mining, working on databases. Thorough knowledge of GCP, ICH guidelines and regulatory requirements for clinical trial conduct.	31,000/- Fixed Per month	Upper age limit for up to 45 years Age relaxation will be as per the Government of India/ICMR rules

5	**Consultant (Clinical research Coordinator)** **Place of Work** ICMR Hqrs., New Delhi **Job Requirement:** The activities of the Consultant would include but not limited to: a. To follow SOPs for a clinical trial. b. To monitor all aspects of study execution including assessing site, capacity building, processes development of various steps of clinical trial; follow study timelines and metrics. c. Job requires frequent all India travel to sites for monitoring, and site audit d. To participate in Site monitoring visits and oversee clinical monitoringactivities ensuring compliance with Good Clinical Practices. e. To prepare and/or review study related Standard Operating procedures andDocuments. f. To develop and manage study master files and site files. g. The job may require travel to the trial sites and attending out station meetings Any other job assigned by the competent authority.	**3 (Three)** **Unreserved**	**Essential:** • Professional having M.Sc in Biomedical sciences or B.Tech (Comp. Sceience, Biotechnology or B Pharm or any equivalent degree from a recognized university with 2 years' experience in biomedical research particularly in clinical studies/trials **Desirable:** • Post graduate degree in relevant subjects • Knowledge of computer applications or business intelligence tools/data management/data synthesis/Report writing, data mining, working on databases.	31,000/- Fixed per month	Upper age limit for up to 45 years Age relaxation will be as per the Government of India/ICMR rules

A walk-in interview is scheduled on 22nd June, 2022, 10:30 A.M. onwards for the following posts for which the details are given below. Interested and eligible candidates for the positions mentioned below may come for the walk-in interview and bring their CV in prescribed format along with all relevant documents and one passport size photograph and any identity card on 22nd June, 2022, 8.30 am onwards till 10:30 AM.

Candidates applying for more than one post should indicate the names of the post clearly on application form. Applicants coming after 11.00 AM on 22nd June 2022 will not be entertained.

All the candidates who wish to appear for the interview should report at Reception, ICMR HQ, V Ramalinga swami Bhawan, Ansari Nagar, New Delhi on 22nd June, 2022 at 8.30AM till 10:30 AM for registration in room No. 322, 2nd floor, ICMR HQ. The verification of the documents of the candidate will start from 8:30 AM onwards and eligible candidates after verification would be interviewed 10:30 AM onwards.

General Terms and conditions: -

1. Number of positions may vary.
2. These positions are meant for temporary projects and co-terminus with the project.
3. Engagement of the above advertised Project Human Resource Positions will depend upon availability of funds, functional requirements and approval of the Competent Authority. Therefore, we are not committed to fill up all the advertised Project Human Resource Positions and the process is liable to be withdrawn / cancelled / modified at any time.
4. The rates of emoluments/stipend shown in this advertisement are project specific and may vary according to sanction of the funding agency of the Project.
5. Cut-off date for age limit will be as on the date of last date for submission of applications.
6. Age relaxation will be as per the guidelines of ICMR.
7. Reserved category candidates must produce their latest Caste Validity Certificate. OBC candidates must possess a latest valid non-creamy layer certificate. PWD candidates shall produce latest disability certificate issued by a Medical board of Government hospital with not less than 40% disability.
8. Separate application should be submitted for each position. Allotment of project to the successful candidates will be decided by the competent authority at its discretion.
9. Qualification & experience should be in relevant discipline / field and from an Institution of repute. Experience should have been gained after acquiring the minimum essential qualification.
10. Mere fulfilling the essential qualification does not guarantee the selection.
11. Persons already in regular time scale service under any Government Department / Organizations are not eligible to apply.
12. No TA/DA will be paid to attend interview / personal discussion and candidates have to arrange transport / accommodation themselves.
13. ICMR reserves rights to consider or reject any application / candidature.

14. Submission of wrong or false information during the process of selection shall disqualify the candidature at any stage.

15. The persons engaged on Project Human Resource Positions cannot be permitted to register for Ph.D., due to time constraints.

16. The persons engaged on Project Human Resource Positions will normally be posted at the study site; however, they can be posted to any other sites in the interest of research work. They are liable to serve in any part of the country.

17. The persons engaged on Project Human Resource Positions shall **not** have any claim on a regular post in ICMR or in any of its Institutes/Centers or in any Department of Government of India and their project term with breaks or without breaks in any or multiple projects will not confer any right for further assignment or transfer to any other project or appointment / absorption / regularization of service in funding agency or in ICMR. Benefits of Provident Fund, Pension Scheme, Leave Travel Concession, Medical claim, Staff Quarters and other facilities applicable to the regular staff of ICMR etc. are **not** admissible to the project human resource positions.

18. Successful candidates will normally be engaged on Project Human Resource Position initially for a period of one year or less, depending upon the tenure of the Project and functional requirements. Continuation / Extension to engagement of Project Human Resource Positions will be depending upon evaluation of performance, tenure of the project, availability of funds, functional requirements and approval of Competent Authority. The maximum term of any Project Human Resource Position in any or multiple projects, with breaks or without breaks shall be five years only. The concerned Project Investigator, Division Head and Head of the host Institute shall personally be responsible and accountable for the continuation / extension given if any without prior concurrence of the Director General, ICMR to any project human resource position beyond five years either with or without breaks in any or multiple projects.

19. ICMR reserves the right to terminate the project human resource position even during the agreed contract period or extended contract period without assigning any reason.

20. Leave shall be as per the ICMR's policy for project human resource positions.

21. Candidate must submit his/her duly filled in application form in the prescribed format with a recent passport size color photograph along with a detailed bio-data/C.V. and all relevant documents; **duly self-attested**; in proof of his/her educational qualifications [all certificates and mark-sheets from 10th Std. onwards], working experience, age, caste and **photo id** [Aadhar Card/Indian Passport/PAN Card/Driving License] etc., within the schedule date and time for submission of application, failing which his/her candidature will not be considered. Late/Delayed/Incomplete/Unsigned applications will not be considered at all and no correspondence will be entertained in this regard.

22. ICMR reserves the right to cancel/modify the process at any time, at its discretion.

23. The decision of the Competent Authority will be final and binding.

24. Canvassing in any form will be a disqualification.

25. Corrigendum/addendum/further information; if any; in respect of this advertisement, will be published on our website only. Hence, the candidates are advised to see our website: https://main.icmr.nic.in/ , regularly for further updates related to this advertisement.

Indian Council of Medical Research

Application for engagement of Project Human Resource Position, purely on temporary basis

1. Name of the Project Human Resource Position, applied for : _____

2. Advertisement No. : _____

3. Name in full (IN BLOCK LETTERS) : _____
   [SURNAME] [NAME] [FATHER/HUSBAND]

Latest photograph

4. Mother's Name : _____
   Father's Name _____
   Husband's Name _____

5. Address for Correspondence : _____
   _____
   _____
   _____
   Contact No._____
   Email id: _____

6. Permanent Address : _____
   _____
   _____
   _____

7. Date of Birth [dd/mm/yyyy] : _____ Age : _____
   (Certificate must be supported)

8. Whether SC/ST/OBC/General : _____ Caste: _____

9. Marital Status : Married / Unmarried / divorcee / widower / widow

10. Educational Qualifications : (Certificates in proof of qualifications must be supported).

SN	EXAM. PASSED	GRADE	YEAR OF PASSING	BOARD / UNIVERSITY	SPECIALIZATION

11. Work Experience (Certificates in proof of experience must be supported):

Name of Employer	Post	From date	To date	Reason for leaving

Total Experience gained after acquiring the minimum essential qualification (in years): _____

12. Details of NET/GATE/National level exams passed, if any.

Exam passed	Date of passing	Valid till

13. If selected what period would you require to join: _____

Note: Additional information, if any can be provided on a separate paper or on overleaf of this page.

Declaration: I hereby declare that the particulars furnished in this form by me are true to the best of my knowledge and belief. Furnishing of false information or suppression of facts will be disqualification and is likely to render the candidate unfit.

Date:_____ Signature: _____

Place:_____ Name of the candidate: _____