India TB Research Consortium

Letter of Interest (LOI) for Intensified Case Finding for pulmonary tuberculosis in Institutional Healthcare Settings

Background: India presents largest burden of tuberculosis (TB) in the world. Despite the availability of improved diagnostic services in the recent past, many people still remain undiagnosed or are diagnosed late. This leads to continuing transmission of disease and higher mortality as well as economic loss and more suffering to patients. Provider initiated Intensified Case Finding (ICF) could be an important tool to identify TB patients amongst high risk populations. However, we lack appropriate algorithms to be used in high risk groups in India. The WHO Global End TB Strategy aims for 90% reduction in TB incidence, 95% reduction in TB deaths and elimination of catastrophic costs due to TB in comparison to 2015 by the year 2035. In India, the strategy is to achieve these goals much earlier i.e. by 2025 as mandated by Government of India.

To achieve the goals of the End TB strategy; novel tools, strategies and magnified efforts are required. Case finding and treatment of TB disease are the primary means of controlling transmission and reducing incidence. ICF has the potential to markedly reduce TB incidence in high burden areas when applied to epidemiologically appropriate settings coupled with strong and effective DOTS programs. Therefore, Indian Council of Medical Research on behalf of India TB Research Consortium solicits Letters of Interest from interested institutes/ organizations in the area of implementation research for TB for a large multi-centric project for which protocol has been developed.

We propose to conduct an implementation study where certain high risk groups like Maternal and Child Health (MCH) clinic attendees (antenatal, post-natal), diabetics, hospitalized patients in medical wards, elderly people and People Living with HIV (PLHIV) visiting ART (Anti Retroviral Therapy) centers will be screened to find out the prevalence of microbiologically confirmed pulmonary TB and to determine the acceptability & feasibility of ICF in these groups. The results obtained will provide vital inputs for incorporation into the programme and the experience gained will be useful for planning its scalability. Implementation studies in other high risk patient groups may be taken up at a later stage.

The lead Investigator and coordinator for this project will be

Dr Vineet Chadha
Head, Epidemiology and Research Division
National Tuberculosis Institute (NTI)
8 Bellary Road
Bangalore

We solicit Letters of Interest from:

1. Medical Colleges/ Research Organizations/Institutions/Universities/Academic Institutions
2. Private hospitals and practitioners/ Non-Government Organisations

Duration of the Study: 1 year

Target Population: The target population would include:

1. Pregnant and post-natal women attending Maternal and Child Health (MCH) clinics of district level public sector hospitals
2. Diabetic patients attending any of the departments of the selected district hospitals – both out-patient and in-patient
3. Elderly (≥60 years) patients attending any of the departments of the selected district hospitals – both out-patient and in-patient
4. Patients hospitalized in medical wards
5. PLHIV: Attending ART centers and those found to be HIV reactive after counselling and testing in ICTC centers

Study Design: Multicentric cross sectional.

Sample Size: The study will include 7,700 subjects in each of the five groups, p=1/37*, α=0.05, ε=0.15, Response rate = 0.8. Sample size for each of five groups will be allocated equally among selected district hospitals / ART-ICTC centers. Within each group, consecutive patients will be enrolled into the study till the required sample size is achieved.

Site of the study: There will be 5 nodal implementing institutes, which may be a medical college or any other institution with sufficient research experience, preferably having access to all the five target populations. Patients' recruitment will take place from secondary level health care facilities i.e., district hospitals – 4 or more for each group.

Ethical Approval: The Participating Institute would have to take ethical approval of the project by Institutional Ethics Committee. In addition the institute must ensure the linkage of patients to treatment.

Selection Criteria: Applicants will be assessed based on the institutional capacity of the investigators and experience in the relevant field as per the details in the attached questionnaire. The investigators would need to apply as multidisciplinary teams (3-4) which would include clinicians, social scientists, epidemiologist, statistician etc). It is important to include representatives from the Revised National Tuberculosis Control Programme (RNTCP) as investigators and this needs to be specified. It is important that the investigators have experience in TB control activities.

How to apply: Interested individuals or groups should submit the LOI along with the attached completed signed Questionnaire. The applications should be addressed to DG, ICMR and sent via e-mail at teamtbconsortium@gmail.com by **23rd June, 2017 by 6:30 P.M.** Shortlisted application sites may be visited by the experts so as to assess and complete the site selection. Trainings as required shall also be provided to the finally shortlisted sites for the study.

INSTITUTIONAL DETAILS	
Name of the Institution/ Organization:	
Name of the Applicant(s): *(Potential Investigator and Co-investigator)*	
Complete Address with contact details of Applicant(s): *(Mention email ids, fax, landline, mobile numbers)*	
Type of Institution: *(ICMR/Medical College/ NGO etc.)*	
Epidemiological study undertaken by you in the area of tuberculosis, *(Provide brief on type, nature and duration of study)* **Has the Institute contributed to any policy changes as a result of Implementation research /epidemiological studies?** *(If yes, please provide details in brief)*	

S. No.	Item/area/activity	Yes	No	NA	Remarks/Comments/Details
1.	**ORGANIZATION AND PERSONNEL**				
1.1	Do you have adequate time to devote for the studies, besides current work load? Please mention number of hours possible to devote everyday				
1.2	How many studies are currently ongoing in at your Department/ Institute/ Organizations in Tuberculosis? *Please provide status of the studies.*				

1.3	Do you have any research staff presently at your site? (*Can they manage an additional study?)*				
1.4	Does your site (department) have professionally trained counsellors to educate patients on TB treatment compliance?				
1.5	Does your site have/ have access to the diabetics, Obst. & Gynae and HIV clinics?				
1.6	Do you have a multidisciplinary team (Please Describe)				
1.7	Does your institution have X-Ray facility: Mobile X ray Unit: (*If yes, please specify number; if no, is your Institute having access to any organization having mobile X-ray Units*)				
1.8	Does your Institution have TB/ MDR-TB diagnostic facilities: (Name the tests available for TB diagnosis)				
2.	**ETHICS COMMITTEE**				
2.1	Does your site have an Institutional Review Board (IRB) constituted as per Schedule Y requirements?				
2.2	Is the IRB registered with CDSCO? *(If yes, please provide the registration letter; if no, is your organization applying for registration to CDSCO, please specify time frame)*				
S. No.	**Item/area/activity**	**Yes**	**No**	**NA**	**Remarks/Comments/Details**
3.	**INFRASTRUCTURE**				
3.1	Is there adequate isolated space to be seated with a subject to administer the Informed consent?				
3.2	Do you have adequate space for seating of a 4-6 membered team for the study and sufficient space to store related documents/ records?				
3.3	Do you have laptops/ desktops at your department which could be dedicated to the study, (*If yes, please specify how many*)				
3.4	Do you have access to statistical software which are used for IR/ OR studies?				
3.5	Does your Institute have access/ linkages to district hospitals?				

S. No.	Item/area/activity	Yes	No	NA	Remarks/Comments/Details
4.	**BIOLOGICAL SAMPLE COLLECTION, PROCESSING & STORAGE**				
4.1	Does the site have access to a specialized Microbiology laboratory for diagnosing TB case inducting following assessments?				
	Microscopy (Bright Field, LED, Fluorescence)				
	Culture (MGIT, LJ, Both)				
	Gene-Xpert				
	Refrigerator				

Please tick the boxes (☑) against target populations for which you would be interested to participate in the study, (*Preference will be given to sites which can implement the study for all categories*):

S No	Category	Interest in Participation	Approximate numbers of individuals which can be covered by the Implementing Institute
1	Pregnant and post-natal women attending Maternal and Child Health (MCH) clinics of district level public sector hospitals	☐	
2	Diabetic patients attending any of the departments of the selected district hospitals – both out-patient and in-patients	☐	
3	Elderly (≥60 years) patients attending any of the departments of the selected district hospitals – both out-patient and in-patient	☐	
4	Patients hospitalized in medical wards	☐	
5	PLHIV: Attending ART centers and those found to be HIV reactive after counselling and testing in ICTC centers	☐	