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**Acknowledgement for GCI-TB-Cachexia Proposal submission -
BT/TEMP20859/GCI-TB-CACHEXIA-11/23**

BIRAC <mdpmubmgf@birac.nic.in>

Wed, Jan 31, 2024 at 1:40 PM

Reply-To: BIRAC <mdpmubmgf@birac.nic.in>

To: nikkuyadav@srhu.edu.in

Cc: mdpmubmgf@birac.nic.in, pmubmgf3.birac@nic.in

Dear Applicant,

This is to confirm that your proposal titled, **Assessment of nutritional supplementation on incidence of TB in the Healthy Household Contacts of Pulmonary TB Index cases in Himalayan Hospital, Dehradun and its field unit at Haridwar in Uttarakhand and elucidating host factors** has been successfully submitted under **GCI-TB-Cachexia**. Temporary reference number of the proposal is **BT/TEMP20859/GCI-TB-CACHEXIA-11/23**. The proposal is being examined for preliminary eligibility requirements.

In case your proposal qualifies the mandatory eligibility criteria, a permanent reference number will be communicated to you. However, if the proposal does not meet the same, it shall not be considered for further review and you would be informed accordingly.

Regards,

Programme Manager

GCI-TB-Cachexia

Note: This is an auto generated email



S.No	General Information	
1	Name and address of the Medical College/ Hospital/ Research Institute/ other facility where the clinical trial will be conducted	Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant 248016 Dehradun, Uttarakhand
1a	Type of Organization	State University under section 2(f) of UGC Act, 1956 vide Uttarakhand State Act in 2013.
2	Name of the Principal Investigator with Designation and Qualification	Dr Rakhee Khanduri Professor and Head Department of Resp Medicine HIMS, SRHU, Dehradun Chairman OR NTEP Uttarakhand MD Respiratory Medicine
2a	Phone number and email id of the Principal Investigator	Contact Number: 7579281136/ 8630474424 rakhee.sodhi@gmail.com
3	Details of Co-Investigators: Name, Designation and Qualification	Dr Rakhee Khanduri (MBBS, MD) Professor and Head Department of Respiratory Medicine HIMS, SRHU, Dehradun Chairman OR NTEP Uttarakhand MD Respiratory Medicine Dr Sushant Khanduri (MBBS, MD) Professor Department of Respiratory Medicine HIMS, SRHU, Dehradun Nodal Officer MD Respiratory Medicine Dr Nikku Yadav (B Pharma M Pharma Ph D) Associate Professor & In-charge

		<p>Department of Clinical Research Head, Clinical Trial Centre HIMS, SRHU, Dehradun</p> <p>Dr Arti Kotwal (MBBS, MD) Professor, Department of Microbiology HIMS, SRHU, Dehradun</p> <p>Dr Kiran Katoch) (MBBS, MD) Former Director National JALMA Institute for Leprosy and other Mycobacterial Diseases, Agra Professor Emeritus, Swami Rama Himalayan University</p> <p>Dr Bindu Dey (B.Sc MSc M Phil Ph D) Former Adviser, DBT Director Research Chairperson Clinical Trial Committee Swami Rama Himalayan University</p> <p>Prof Ashok Deorari (MBBS MD) Former Head Department of Pediatric AIIMS New Delhi Pro-VC SRHU Swami Rama Himalayan University</p>
4	<p>Research Team (<500 words) Summarize and justify the composition of the research team, based on the expertise of the individual team members in conducting the trial.</p>	<p>Research Team Summary and Justification</p> <p>The proposed research team brings-in expertise on respiratory medicine, microbiology, clinical research, Tuberculosis policy & NTEP implementation and regulatory compliance ensuring the scientific, operational, and ethical robustness.</p> <p>Dr. Rakhee Khanduri, Professor & HOD, Department of Respiratory Medicine as the Principal Investigator has two decades of clinical and academic experience. As Chairperson of the State Task Force on National Tuberculosis Elimination Program (NTEP) in Uttarakhand, she plays a pivotal role in state-level public health</p>

	<p>planning and program implementation on TB. She has led multiple institutional and collaborative clinical studies on respiratory and infectious diseases. Her leadership would ensure meeting commitment on the number of patients, scientific rigor, clinical accuracy, regulatory compliance, and ethical oversight across all stages of the trial.</p> <p>Dr. Sushant Khanduri, Professor, Department of Respiratory Medicine as a Co-Investigator is MD in Respiratory Medicine. He is a practicing pulmonologist with experience in managing a wide spectrum of respiratory conditions, including tuberculosis, asthma, interstitial lung disease, and chronic obstructive pulmonary disease. He has actively contributed to multiple clinical audits and observational studies. His role will focus on patient recruitment, clinical assessment, treatment monitoring, and adverse event reporting, thereby ensuring high-quality data collection and patient safety.</p> <p>Dr. Nikku Yadav, Associate Professor, Department of Clinical Research, SRHU, brings substantial experience in epidemiology, clinical trial design, biostatistics, Data capture and data monitoring. She has coordinated several academic and government-funded trials, with a focus on public health, data analytics, and outcome research. Dr. Yadav will support the development of the study protocol, define key performance indicators, conduct interim & final statistical analyses, ensuring that the trial methodology aligns with scientific best practices and regulatory standards.</p> <p>Dr. Arti Kotwal, Professor, Department of Microbiology, a lead of the laboratory component of the project brings extensive expertise in clinical microbiology, including bacteriology, virology, antimicrobial resistance, and diagnostic microbiology. Dr. Kotwal will oversee the collection, transport, and analysis of biological samples, ensuring adherence to biosafety protocols and laboratory quality assurance standards. Her role is crucial for confirming clinical diagnoses, analyzing microbiological trends, and supporting the interpretation of lab-based outcomes in the context of the trial.</p> <p>Dr Kiran Katoch brings-in about forty-four years of experience in Leprosy and Tuberculosis diagnosis & treatment protocols and related health problems of rural population. She has been instrumental in establishment of Model Rural Health Research Unit at Ghatampur, Kanpur, UP. She brings with her the accuracy of trial design, choice of doses and PK/PD aspects of rifampicin and other quinolones during trials.</p> <p>Dr. Bindu Dey brings three decades of scientific leadership in biotechnology, clinical & translational research, and innovation management. As Adviser in DBT, she conceptualized TB Consortium and funded multicentric trials of TruNat leading to its use for TB and MDR in NTEP. She coordinated multicentric trials for</p>
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		<i>Mycobacterium indicus pranii</i> as an adjunct to ATT in Cat II PTB patients. She is associated with TB Vaccine component of TB Consortium, ICMR. She brings adoption of all regulatory procedure and accurate data capture and analysis.										
5	Does the investigator and/or site staff have experience in conducting clinical trials?	<p>Yes;</p> <p>Drs Rakhee Khanduri and Sushant Khanduri are full-time clinicians in the respiratory Medicine of the HIMS. Every OPD, they see more that 50 TB patients and deal with the diagnosis and treatment profiling. They have conducted hospital based clinical studies and also oversee the Poshan Abhyaan programme of the Hospital in close association with the Rural Development Institute under SRHU. The University through its outreach Institute has adopted about 1000 TB Patients and provide them nutritional food as per the Govt of India Policy for TB patients.</p> <p>Two applicants of this proposal have a cumulative experience of 40 years of doing clinical trials and field validation of bio-based products. As Head of Department of Clinical Research, Dr Nikku Yadav oversees & ensures GCLP compliance to regulatory trials going at CTU specially from pharma companies.</p> <p>Dr. Bindu Dey has been involved in trials of TB TruNat with ICMR, <i>MIP</i> with Cadilla Pharmaceuticals, Cholera vaccine, the first GMO of the country ensuring all safety compliance of IBSC, RCGM and DCGI. She has engaged with many CRO working on Clinical Trials including CDSA of THSTI.</p> <p>The team has sufficient experience of conducting ICH-GCO+P compliant studies in areas of covering onc Medicine, Dermatology, Neurology and traditional Medicine. HIMS can design, plan and execute single or multi-centric trials as also cohort-based studies. HIMS, SRHU has a 1200- bedded hospitals and a 250-bedded hospital at its Cancer Research Institute. In addition, the Rural Development Institute has adopted 2000 villages where outreach activities into 5 social development areas, i.e., Skill Development; Healthcare; Education; Malnutrition; Water & Sanitation are undertaken.</p>										
5a	If yes, please attach list of research activities for investigator and/or site staff for the last 5 years, including indication, phase of study, type of TB (e.g., DS/MDR/XDR), current study status (closed/ongoing), and number of Participants											
	<table><tr><th>S.No</th><th>Title of the work</th><th>Year</th><th>Status</th><th>Number of Participants</th></tr><tr><td></td><td></td><td></td><td></td><td></td></tr></table>	S.No	Title of the work	Year	Status	Number of Participants						
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1	Molecular Characterization of Mycobacterium Tuberculosis Isolates From Extrapulmonary Tuberculosis (EPTB) Patients At A Tertiary Care Hospital of Uttarakhand	2025	Completed	612
2	Prevalence And Clinical-Radiological Profile of Type 2 Diabetes Mellitus In Drug-Resistant Pulmonary Tuberculosis Patients	2023	Completed	104
3	A Study To Determine Anxiety And Depression Among Patients With Drug Resistant Pulmonary Tuberculosis In A Tertiary Care Hospital	2023	Completed	90
4	Study On The Ocular Manifestations In Patients Taking Antitubercular Treatment In The Tertiary Care Centre Of Dehradun	2023	Completed	75
5	High Resolution Computed Tomography (Hrct) In Diagnosis of Sputum Smear Negative Presumptive Pulmonary Tuberculosis Patients	2022	Completed	96
6	Study of Clinico-Radiological Profile of Patients With Spinal Tuberculosis	2021	Completed	54
7	Prevalence And Distribution of Various Hpv Genotypes In Women With High Risk For Cervical Carcinoma	2020	Completed	384
8	Factors Determining Hepatotoxicity In Patients On 1st Line Att	2019	Completed	180
9	A Microbiological Study of Extrapulmonary Tuberculosis In Patients Attending A Tertiary Care Centre	2019	Completed	422
10	Microbiological Profile of Neonatal Septicemia In Neonatal Intensive Care Unit	2019	Completed	124
11	Pleural Fluid Adenosine Deaminase, C -Reactive Protein Levels And Lymphocyte/ Neutrophil Count Ratio In Differentiating Tubercular And Non-Tubercular Pleural Effusion	2018	Completed	60
12	Comparison Of Ziehl-Neelson Staining And Fluorescent Staining In Suspected Cases Of Tuberculosis	2018	Completed	200
13	Level Of Inflammatory Markers And Their Association With Sympathetic Function In Prehypertensive Young Male Adults	2018	Completed	80
14	Study of The Clinico-Etiological Profile Of Fungal Keratitis In A Tertiary Care Hospital In North India	2017	Completed	53
15	Study of Polymerase Chain Reaction In Cerebrospinal Fluid For Diagnosis Of Tubercular Meningitis	2016	Completed	3
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	16	To Assess Diagnostic Utility of Pleural Fluid Adenosine Deaminase (Ada), Interferon Gamma (Ifn), Lymphocyte/Neutrophil Ratio (L/N) And Its Combination In Differentiating Tubercular And Non-Tubercular Exudative Pleural Effusion	2015	Completed	9 0
	17	A Clinico-Mycological Profile of Fungal Skin Infections Caused by Dermatophytes	2013	Completed	1 0 9
5b	Collaboration with ICMR or contribution to ICMR activities in last 5 years (maximum 250 words) Two levels of association exist with the ICMR; First level pertains to implementing Research Projects sanctioned by the ICMR; and secondly, the association of Advisers of SRHU with ICMR R & D committees. Projects sanctioned: a Hospital-based cancer Registry at the Cancer Research Institute, SRHU in 2022-23; CRISPI study on Chronic Respiratory Illness sanctioned in 2022-23; a cross-sectional survey on Human Rabies Deaths and Animal Bite Burden sanctioned in 2022-23; Standard Treatment Workflows for pediatrics to improve adherence to district hospital guidelines under District Residency Program of NMC 2021 in 2023-24; part of a 10-centre SANKALP project to achieve single-digit neonatal mortality in 2023-24; a Hospital-based Stroke Registry sanctioned on 1.04.2024 till 2027. The NABL accredited Microbiology Lab of SRHU was recognized by the ICMR for testing of SARS COVID 19 by Real time PCR in the year 2020. SRHU has been sanctioned two Advanced Training programmes by the DHR i.e. Advanced Molecular tools for Healthcare; and Training on Good Clinical Practices in the F.Y 2024-25. The Advisors of SRHU have been closely associated with Policy Framework on Neonatal Mortality (Dr A.K.Deorari); validation of TruNat and its introduction in TB Eradication Programme; TB vaccine Expert Group under TB Consortium (Dr Bindu Dey); Dr Kiran Katoch, Former Director, JALMA, Agra has joined as Professor of Eminence; she has been associated with R & D; policies on Infectious Diseases (Leprosy) and setting-up of Model Rural Health Units (MRU/MRHUs) as exemplified at Ghatampur.				
6	Incidence of TB in your TU/District/State	The Honourable Governor of Uttarakhand launched 'Pradhan Mantri TB Mukht Bharat Abhiyan' under NTEP on 17 September 2022 to support TB patients for nutrition, testing and treatment etc. Groups & Individuals from different walks of life have been associated for providing support to TB patients as Ni-Kshay Mitra. There are 13 District Tuberculosis Control Centres, 98 TB Units at the block level and 157 Sputum Testing Centres in the state. Facility for testing TB through modern technology is available in all the blocks of the state, the total number of NAT machines is 131. For the treatment of DRTB patients, facilities are functional in Government Medical College, Haldwani and <u>Himalayan Institute Medical College, SRHU Jolly Grant, Dehradun</u> . Work of setting up DRTB site in Government Doon Medical College, Dehradun is in process. SRHU is undergoing the process of the recognition as the State Nodal Center for TB & MDR diagnosis using conventional and molecular methods. The case has been duly forwarded by the State TB Office to the Central TB Division (CTD), Ministry of Health & Family Welfare.			

		<p>The National TB Prevalence Survey (2019–2021) and India TB Report 2024 indicate that TB remains a significant public health issue in Uttarakhand, with a higher prevalence in rural and hilly areas. Drug-resistant TB (DR-TB) is emerging as a concern, especially among previously treated patients in Uttarakhand. The NDRS report mentions 20% Drug Resistant TB in previously treated as against the national figure of 11.62%. Although national control programs have improved TB management, Uttarakhand continues to report missed and undiagnosed cases, especially in hill districts (e.g., Pithoragarh, Chamoli, Uttarkashi) which remain silent TB reservoirs in rural communities which may contribute to sustained transmission. Evidence-based policymaking requires localized epidemiological data, especially for states like Uttarakhand. At HIMC, a unit of SRHU, the total samples processed were 5456 in the year 2024 with 641 positive for TB and among these 24 were Rifampicin Resistant.</p> <p>Despite such facilities, HIMC, SRHU see the following:</p> <ul style="list-style-type: none"> • DS TB (New): ~500 • DS TB (Previously treated): ~50 • HIV-TB: ~05
7	<p>How many drug sensitive TB cases are diagnosed in your Institution or hospital every year? Note adult's vs children</p>	<p>i. Adults ~ 500 ii. Children >14y ~ 50</p>
8	<p>How many drug sensitive pulmonary TB cases could be enrolled in the trial in a month?</p>	<p>About 30 after meeting Inclusion/exclusion criteria</p>
Site Infrastructure and Facility		
9	<p>Is your college/ institution attached with Laboratory facility</p>	<p>Bacteriology: Yes/No Biochemistry: Yes/No Hematology: Yes/No</p> <p>Yes; the University has a separate building i.e., Central Research Laboratory that houses three state-of-the-art Diagnostics labs, i.e. Microbiology; Biochemistry and Pathology on three floors. In microbiology lab, investigations related to bacterial, viral, fungal and other micro-organisms are routinely conducted. An advanced biomedical infrastructure exists with RT-PCR, Flow Cytometry, and Molecular Diagnostics set-up complemented by high-end clinical facilities including PET-CT, MRI, Bone Marrow Transplant Unit, and</p>

		<p>Nuclear Medicine. The Diagnostics system is functional through pneumatic system of transport to avoid human interference and contamination.</p> <p>Our Clinical Trial Lab has a Comprehensive Trial Infrastructure that has regulatory compliance. It includes GCLP-compliant lab-setup, facilities to promote Phase 1-3 trials, regulatory back-up, ethical bodies and facilities for trial monitoring and data capture.</p>
9a	If no, Is it attached with any external lab and its distance from site	NA
9b	Does the local laboratory perform sputum smears, mycobacterial cultures and drug susceptibility testing?	Yes
10	Availability of Chest X-ray facility	Yes
11	Is there an In-Patient facility for TB patients available on site/close to the site? If yes, provide details below (name, address, distance from site)	Yes, IPD facility available in our 1200 bedded hospital
12	Does the site have a registered (DHR/CDSCO) local IEC to oversee the trial?	Yes
13	If no, which ethics committee is the site/institution attached to?	NA
14	Does the site have storage facility (both for CRFs and Drugs)	Yes

15	Name and Signature of the person providing the details	<p>Dr Bindu Dey, Director Research Swami Rama Himalayan University, Dehradun</p> <p><i>Nikku Yadav</i></p> <p>Dr Nikku Yadav In-Charge Clinical Trial Centre Swami Rama Himalayan University, Dehradun</p>
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