

Project Proposal for Submission INTENT
Last Date of Submission 22 May 2024

PI Detail

Dr Jayanti Semwal
Professor
Department of Community Medicine
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun
Uttarakhand
91+9412008770
Email Id: jayanatisemwal@srhu.edu.in

Other Member

Technical Advisor

Dr Bindu Dey
Director Research
Swami Rama Himalayan University
Dehradun
Uttarakhand
01352471105
Email Id: director.research@srhu.edu.in

Technical Consultant

Dr Ashok Kumar Deorari
Principal
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun
Uttarakhand
01352471158
Email Id: principal.hims@srhu.edu.in

Co Investigators Details

1. Dr Rajeev Bijalwan
Deputy Director
Rural Development Institute
Swami Rama Himalayan University
Dehradun
Uttarakhand
91+91+9410153938
Email Id: rbijalwan@hihtindia.org

2. Dr Nikku Yadav
Coordinator Clinical Trial Centre
Assistant Professor Clinical Research
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University



Dehradun
Uttarakhand
91+9711197679
Email Id: nikkuyadav@srhu.edu.in

3. Dr Ankit Batra
Assistant Professor
Department of Medical Oncology
Cancer Research Institute
Swami Rama Himalayan University
Dehradun
Uttarakhand
91+9411712969
Email Id: drbatraankit@gmail.com

4. Dr Ashwani Bhat
Associate Professor
Department of Neurology
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun
Uttarakhand
91+9073336334
Email Id: dr.ashwanibhat@gmail.com

4. Ms Akanksha Uniyal
Lecturer
Department of Biostatistics
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun
Uttarakhand
91+7906078248
akankshauniyal97@gmail.com

5. Dr. Deepti Nagrath
Research Scientist,
Department of Community Medicine
Himalayan Institute of Medical Sciences
Swami Rama Himalayan University
Dehradun
Uttarakhand
91+ 8130199091
Email Id: deepti.281190@gmail.com

Number of randomized controlled trials designed/ initiated by the applicant and/or any of the members of the team in last 5 years (give title, funding source, CTRI registration number; indicate if these were regulatory, i.e., required approval from CDSCO and if these were community-based or hospital-based trials):

*

Year	Project	Funding Agency	Funding	CTRI registration number	Regulatory/ Hospital/ Community
2023	Chronic Respiratory Illness In Selected Population Groups in India: ICMR Task Force	Indian Medical Research Council	2.5 Cr	-	Community Based Trial
2023	Reduction of Neonatal mortality in Haridwar dist, UK	Indian Medical Research Council	6.5 Cr	-	Community Based Trial
2021	A comprehensive approach to substance abuse amongst adolescents and youth in rural Dehradun- EK KOSHISH	Uttarakhand Council of Science and Technology (UCOST)	6.94 Lakh	-	Community Based Trial
2021	A comprehensive approach to substance abuse amongst adolescents and youth in rural Dehradun- EK KOSHISH Extension: Vikas Nagar District	Uttarakhand Council of Science and Technology (UCOST)	6.14 Lakh	-	Community Based Trial
2021	Impact of yoga asanas, on quality of life of patients with type 2 diabetes and non-alcoholic fatty liver disease (NAFLD): a hospital based (quasi experiment) study	-	-	CTRI/2024/03/064485	Hospital Based Trial
2020	Establishment of population specific reference range of thyroid hormones in iodine deficient population during pregnancy: Uttarakhand Himalaya	Uttarakhand Council of Science and Technology (UCOST)	5.46 Lakh	-	Hospital Based Trial
2020	Assessment of multimorbidity combinations of oral and systemic illnesses in adults and evaluation of a new model for patient centric oral care in Dehradun district	Swami Rama Himalayan University	-	-	Community Based Trial
2019	Two-drug versus three-drug induction chemotherapy in pediatric acute myeloid leukemia: a randomized controlled trial	Cancer Institute (WIA) Adyar, Chennai, India	-	CTRI/2014/11/005202	Hospital Based Trial
2018 – 2023	A randomized controlled trial to compare the efficacy of two different doses of maternal Vitamin B-12 supplementation in improving infant B12 deficiency and neurodevelopment - "MATCOBIND - Maternal Cobalamin (Clinical Trial)"	UCL Great Ormond Street Institute of Child Health & Medical Research Council (MRC) & Department of Biotechnology, Government of India	2.6 Cr	-	Hospital Based Trial
2015-2019	Exploring the feasibility of a school-based intervention to reduce sugar	Indian Medical Research Council	1.2 Cr	-	Community Based Trial

	sweetened beverage consumption in India: A Feasibility Trial				
2018	A study on barriers related to prevention and management of acute respiratory infection among mothers of under five children with a view to develop and evaluate a need based interventional package in selected rural community of Delhi	Swami Rama Himalayan University	-	-	Community Based Trial
2018	A study to assess the effectiveness of nurse led cognitive stimulation program (NLCSP) on Cognitive functions and quality of life among elderly in the selected rural community of Panipat, Haryana	Swami Rama Himalayan University	-	-	Community Based Trial
2017	Effectiveness of comprehensive nursing interventions on well being and quality of life among senior citizen in rural community, Nepal	Swami Rama Himalayan University	-	-	Community Based Trial
2017	"A study to develop and evaluate the effectiveness of a need- based, interventional package on awareness and self-efficiency of primary caregivers in care of children during primary immunizations in selected health facilities of Solan, Himachal Pradesh."	Swami Rama Himalayan University	-	-	Community Based Trial

Number of randomized controlled trials participated in by the applicant and/or any of the members of the team in last 5 years (give title, lead institution, funding source, CTRI registration number; indicate if these were regulatory, i.e., required approval from CDSCO and if these were community-based or hospital-based trials):

Year	Title	Lead Institution	Funding	CTRI registration number	Regulatory/Hospital/Community
2024	A Phase IV Multi-Centric, Post-Marketing Study Evaluating the Safety, Immunogenicity and Efficacy of the Marketed Formulation of Hetero-Trastuzumab in Female Patients with HER2+ Breast Cancer	Hetero Biopharma Ltd	Hetero Biopharma Ltd	CTRI/2024/01/061144	Regulatory Trial
2024	A Prospective, Randomized, Open-labelled, Multi-centric, Parallel-group, Phase III study to Assess the efficacy and safety of febuxostat ER tablet 40/80 mg versus febuxostat IR tablet 40/80 mg for treatment of chronic-hyperuricemia in conditions where depression has already occurred (including a history, or	Vivotech Research Lab Pvt. Ltd	Vivotech Research Lab Pvt. Ltd	-	Regulatory Trial

	presence of tophus and/ or gouty arthritis				
2024	A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Camizestrant (AZD9833, a NextGeneration, Oral Selective Estrogen Receptor Degradar) Versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) as Adjuvant Treatment for Patients with ER+/HER2- Early Breast Cancer and an Intermediate-High or High Risk of Recurrence Who Have Completed Definitive Locoregional Treatment and Have No Evidence of Disease	Astra Zeneca Ltd	Astra Zeneca Ltd	NCT059 52557	Regulatory Trial
2024	A post marketing surveillance study to assess safety and tolerability of Liposomal Amphotericin B Injection (GUFISOME) in patients with Invasive Fungal Infection who are refractory to or intolerant of conventional Amphotericin B therapy	Gufic Biosciences Limited	Gufic Biosciences Limited	CTRI/20 22/08/0 44680	Regulatory Trial
2024	A phase III, Open label, randomized study of neoadjuvant datopotamab deruxtecan (Dato DXd plus Durvalumab followed by adjuvant durvalumab with or without chemotherapy followed by adjuvant pembrolizumab with or without chemotherapy for the treatment of adult patients with untreated triple- negative or hormone receptor low/HER2- negative breast cancer	Astra Zeneca Ltd	Astra Zeneca Ltd		Regulatory Trial
2023	Chronic Respiratory Illness In Selected Population Groups in India: ICMR Task Force	Swami Rama Himalayan University	Indian Council of Medical Research		Community Based Trial
2023	Reduction of Neonatal mortality in Haridwar dist, UK	Indian Medical Research Council	Indian Council of Medical Research	-	Community Based Trial
2023	A phase III, prospective, Randomized , Multicentre. Comparative, Double Blind, Parallel group study to investigate the efficacy, safety and pharmacokinetics of ZRC-3276 versus Opdivo (Nivolumab) in subjects with locally advanced or	Zydus Life Sciences	Zydus Life Sciences	CTRI/20 22/12/0 47923	Regulatory Trial

