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 Unique Doc. Reference : SUBIN-DL78170389024366482312V
 Purchased by : DIRECTOR GENERAL CCRH NEW DELHI
 Description of Document : Article 5: General Agreement
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 (Zero)
 First Party : DIRECTOR GENERAL CCRH NEW DELHI
 Second Party : DIRECTOR NATIONAL INSTITUTE OF SOWA RIGPA LEH LADAKH
 Stamp Duty Paid By : DIRECTOR GENERAL CCRH NEW DELHI
 Stamp Duty Amount(Rs.) : 100
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MEMORANDUM OF UNDERSTANDING

TO UNDERTAKE RESEARCH STUDY TITLED "TO EVALUATE THE EFFICACY OF HOMOEOPATHIC MEDICINE COCA, ACETAZOLAMIDE, AND COCA AS ADD-ON TO ACETAZOLAMIDE AS PROPHYLAXIS AGAINST ACUTE MOUNTAIN SICKNESS: A PROSPECTIVE, TRIPLE ARM, RANDOMISED PILOT TRIAL"

6.02.2023

06/02/2023

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This Agreement is made on 06.02.2023 by and between the Central Council for Research in Homoeopathy (CCRH), Delhi, an autonomous organization under the Ministry of AYUSH and is registered under the Societies Registration Act XXI, 1860, having its registered office at Jawahar Lal Nehru Bhartiya Chikitsa Avum Homoeopathy Anusandhan Bhawan, 61-65, Institutional Area Janakpuri, New Delhi-110058 hereinafter called "CCRH", through its Director General, as the first party.

AND

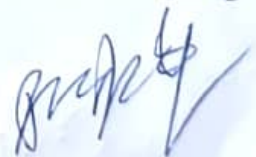
National Institute of Sowa- Rigpa, Leh, Ladakh which is an autonomous institute under the Ministry of AYUSH and is registered under the Societies Registration act XXI of 1860 in the Union Territory of Ladakh with its registered office in Leh town herein called "NISR" through the Director, as the second party.

for undertaking the research study titled "To evaluate the efficacy of Homoeopathic medicine Coca, Acetazolamide, and Coca as add-on to Acetazolamide as prophylaxis against Acute Mountain Sickness: A prospective, triple arm, randomised pilot trial" herein called Coca study as per the protocol developed by CCRH and duly approved in its 19th meeting of Special Committee for Clinical Research and 28th Central Ethical Committee meeting.

Article 1 **INTRODUCTION**

CCRH, through its network of Institutes/Units across the country, has been conducting various kinds of research on scientific lines in the field of Homoeopathy since 1978. NISR is established for providing quality education, research, and health care in Sowa-Rigpa while providing good clinical care to the public. It aimed to develop as an apex human resource development centre of Sowa-Rigpa medicine knowledge with linkages to the current health care system.

Both organizations share areas of common interest in the field of research. In some of these areas, the degree of mutual interest is so great that considerable advantage may be gained from their pursuit on a collaborative basis.



Article 2
PURPOSE AND SCOPE

Both parties have agreed to the purpose and scope indicated below:

A. PURPOSE

Conducting research project "Coca study" in Homoeopathy as mutually agreed upon.

B. SCOPE

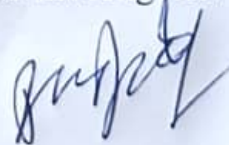
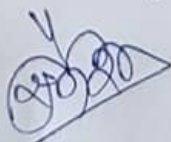
The general area of interest of the collaboration will include Coca research study and any other areas of research of mutual interest to CCRH and NISR.

The collaboration will be established within the principles set out in the following sections, which will be reviewed by both parties once a year or as required.

Article 3
RESPONSIBILITIES OF CCRH AND NISR, LEH

A. CCRH:

- i. To engage and depute Research Associates (scientists) / Senior Research fellow's (SRF) to undertake the research on the Coca study developed by the council as per study protocol.
- ii. To depute appropriate supportive staff as per the requirements of the research study protocol.
- iii. To provide study-related stationary, desktop/ laptop, case records, investigation equipment etc., as per the requirement of the study protocol.
- iv. To provide medicines (Homoeopathic medicine Coca and allopathic medicine Acetazolamide), and other laboratory investigations as per the requirement mentioned in the protocol.
- v. To engage and depute an allopathic consultant, under specified terms and conditions for the Coca study.
- vi. Regular monitoring and review of the project by site visits by the Study Coordinator/ Principal Investigator at CCRH Headquarters as per the requirement of the protocol.
- vii. Implementation of the study protocol through its site principal investigator.



B. NISR:

- i. To provide the location and adequate space for the research team deployed in NISR as the study site.
- ii. To provide help to contact local agencies like tourist hotels, trekking or Marathon organizers so that the target study population can be approached.

Article 4

FINANCIAL ARRANGEMENTS

- A. The financial arrangements to cover expenses for human resources, stationary, desktop/ laptop, fieldwork expenses, medicines, and other laboratory investigations as per the requirement of the protocol shall be borne by the CCRH.
- B. Notwithstanding anything contained in paragraph (A) above, expenses for organizing the meetings and conferences within the framework of this Memorandum of Understanding shall be borne by the party hosting the events. The party, which is sending its representatives for participation in the said events if any, shall bear their own travel and boarding expenses.

Article 5

PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

A. GENERAL CLAUSES:

- i. The patent, if any, found as an outcome of research projects undertaken at the research study sites will be applied by the CCRH, who shall make efforts to commercialize the product if applicable.
- ii. The investigator or staff employed for the research projects shall not obtain intellectual property rights without prior approval of the CCRH.

B. PUBLICATION:

The original papers on the primary and secondary outcomes emerging from the study will be published by the CCRH. The names of the scientists who have participated and contributed significantly in the protocol development, collection of data at the site, data analysis, manuscript preparation, revising the manuscript and final approval of the manuscript will be considered for authorship of the manuscript. NISR will be duly acknowledged for their contribution as the study site as per the ICMJE guidelines for authorship at the time of publication of manuscripts.

C. CONFIDENTIAL INFORMATION:

All information collected in the study will be kept strictly confidential, except as required by the law of the land. Privacy and confidentiality will be honoured



and identifying information pertaining to any patient shall be coded and not disclosed at the time of publication/presentation of study results.

Article 6

REVISION, MODIFICATION AND AMENDMENT

Either Party may request in writing any revision, modification or amendment of all or any part of this Memorandum of Understanding;

- A. Any revision, modification or amendment agreed to by the Parties shall be in writing and form part of this Memorandum of Understanding.
- B. Such revision, modification or amendment shall come into force on the date of their signature; and
- C. Any revision, modification or amendment shall not prejudice the rights and obligations arising from or based on this Memorandum of Understanding prior to or up to the date of such revision, modification or amendment.

Article 7

SETTLEMENT OF DISPUTES

Any difference or dispute between the Parties concerning the interpretation and /or implementation and /or application of any of the provisions of this Memorandum of Understanding shall first be settled amicably through mutual consultation and /or negotiation between the Parties, failing which it should be resolved Arbitration under the provisions of Indian Arbitration and Conciliation Act, 1996.

Article 8

FORCE MAJEURE

As agreed by both the parties, neither of them shall be held responsible for non-fulfilment of their respective obligations under this agreement due to exigency of one or more of the events such as but not limited to acts of god, war, flood, earthquake, epidemics, riots, civil commotion and things like that provided that the occurrence and cessation of any such events, the party affected thereby shall give notice in writing within 01 (one) month of such occurrence or cessation. If conditions continue beyond six months, the parties shall then mutually decide the future course of action.



Article 9

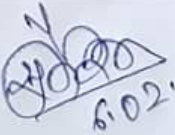
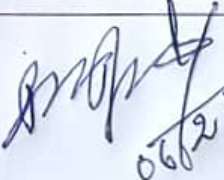
EFFECTIVE DATE & TERMINATION OF THE AGREEMENT

It has been mutually agreed that the following provisions will apply in this case:

- A. The effective date of the MOU will be 06.02.2023 and shall remain in force for 03 years from the said date. The agreement shall terminate on the expiry of the period unless extended by both parties.
- B. Termination during tenure of the Agreement:
During the period of Agreement, parties hereto can terminate the agreement either for breach of any of the terms and conditions of this agreement or otherwise by giving 03 (three) month notice in writing to the defaulting party. Failure of either party to terminate the agreement on account of breach or default by the other shall not constitute a waiver of that party's right to terminate this agreement.
- C. In the event of termination of the Agreement, the rights and obligation of the parties thereto shall be settled by mutual discussion; the financial settlement shall take into consideration not only the expenditure incurred but also the expenditure committed by the parties hereto.

IN WITNESS **WHEREOF** the undersigned, being duly authorized thereto by their respective Parties, have signed this Memorandum of Understanding.

DONE at New Delhi on this 6.02.2023 in two (2) originals.

FOR THE CENTRAL COUNCIL FOR RESEARCH IN HOMEOPATHY, NEW DELHI (Signature with seal)	FOR, NATIONAL INSTITUTE OF SOWA- RIGPA, LEH, LADAKH (Signature with seal)
 6.02.2023	 06/2/2023
(Dr. Subhash Kaushik) Director General Central Council for Research in Homoeopathy	(Dr. Padma Gurmet) Director National Institute of Sowa- Rigpa, Leh, Ladakh

डॉ. सुभाष काशिक / Dr. Subhash Kaushik
महानिदेशक / Director General
केन्द्रीय होम्योपैथी अनुसंधान परिषद्
Central Council for Research in Homoeopathy
(आयुष मंत्रालय, भारत सरकार)
(Ministry of AYUSH, Govt. of India)
61-65, संस्कृत क्षेत्र, 'डी' ब्लॉक के सामने जनकपुरी, नई दिल्ली-110058
61-65, Institutional Area Opp. 'D' Block, Janakpuri, New Delhi-110058