Z. 28015/209/2015-HPC (EMR)-AYUSH

GOVT. OF INDIA
MINISTRY OF AYUSH
EMR DIVISION

AYUSH Bhawan, INA,

New Delhi, dated 4/6/2020

OFFICE MEMORANDUM

Subject: Instructions regarding research proposals to Ministry of AYUSH and its Research Councils in a systematic manner- regarding following of,

This Ministry has been receiving several request regarding clinical trials of AYUSH Medicines/intervention related to COVID-19 including validation of proprietary medicines. In the wake of COVID-19 caused by SARS CoV 2, there has been significant increase in receipt of number of project proposals by Ministry of AYUSH claiming possible treatment of COVID 19.

2. Indian Traditional Medicines have wide potential for usage in such conditions owing to their longstanding use in the community, huge number of ancient reference and large number of publications in scientific journals on their phyto-chemical constituents, mode of action, clinical efficacy etc. At the same time, it is also essential to have scientific evidence on use of any Ayurveda, Siddha or Homeopathy formulation on prevention/management of COVID 19. Therefore, it is felt necessary to make serious efforts for development of drugs based on any of AYUSH systems recognized under Drugs and Cosmetics Act, 1940.

3. The Ministry of AYUSH has issued a notification vide F. No. L.11011/8/2020/AS on 21.04.2020 regarding mandatory requirements for organization for undertaking clinical research for more scientific credibility through evidence based approach. The notification also highlights various issues such as compliance of ethical, regulatory as well as scientific

requirements for bio-medical and health research on human participants. (https://www.ayush.gov.in/docs/127.pdf)

4. Regarding clinical studies and validation of proprietary medicines, the compliance as mentioned in the notification are applicable.

5. The applicants who are approaching Ministry of AYUSH for support of grants-in-aid for clinical studies/validation of AYUSH proprietary medicines under Extra Mural Research scheme of Ministry of AYUSH/collaboration research with Research Councils under Ministry of AYUSH (CCRAS, CCRUM, CCRH, CCRS) require to comply the following:

(i) Sharing of IPR and commercial rights with the funding organization as per their policies.

(ii) Submission of Complete Drug Dossier/Common Technical Documents (CTD) of proprietary and new combination comprising of quality, preclinical safety and any preliminary clinical data/supporting evidences substantiating towards new proposed indication as per requirements.

(iii) They may approach for details of various guidelines related to AYUSH Research (Clinical research protocol, guideline for AYUSH clinical research for COVID-19 etc.) on www.ayush.gov.in

6. All the stakeholders may please refer to the aforesaid instructions for furtherance of their research ideas in a systematic manner.

(Kundan Bharati Sinha)
Under Secretary to the Govt. of India

To

1. State Principal Secretaries (Health/AYUSH)
2. DGs/Director- CCRAS/CCRUM/CCRH/CCRS/ CCRYN
3. Director, AIIA/National AYUSH Institutes