(To be published in the Extraordinary Gazette of India)

Ministry of AYUSH
Government of India

F.No. L.11011/8/2020/AS
Government of India
Ministry of AYUSH

Date: 21st April, 2020.
New Delhi

NOTIFICATION

No. L.11011/8/2020/AS: In the wake of COVID-19 caused by SARS CoV 2, there has been surge in proposals received by Ministry of AYUSH for claiming possible treatment of COVID19. At present, there is no approved treatment for COVID 19 infection. Indian Traditional Medicines have wide potential for usage in such conditions owing to their longstanding use in the community, huge number of ancient references 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, Unani, 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.

2. There are no specific regulatory provisions in the Drugs & Cosmetics Rules 1945, for conduct of clinical trials of Ayurveda, Siddha, Unani and Homeopathy drugs. At the same time it is also necessary that the clinical data generated is scientifically valid and credible. In this context the Ministry has undertaken consultation with DCGI, CDSCO as well as other research experts.

3. In the above background and based on the consultation of CDSCO, the Ministry of AYUSH with the approval of Minister of State Independent Charge for AYUSH notifies that scientists, researchers, clinicians of any of recognized systems of medicine under IMCC Act, 1970, HCC Act 1973 and NMC Act 2019 (formerly IMC Act 1956) can undertake research on COVID19 through Ayurveda, Siddha, Unani and Homeopathy systems including prophylactic measures, intervention during the quarantine, asymptomatic and symptomatic cases of COVID -19, public health research, survey, lab based research etc. to generate evidence.

4. While undertaking research, it is mandatory for the organizations to comply with the following conditions:

i) The proposals should be approved by their scientific advisory bodies and Institutional Ethics Committees.
ii) If it is clinical trial, the project should be registered with CTRI.
iii) The sample size should be based on statistical justification.

iv) The Clinical research should be conducted as per AYUSH guidelines for Clinical Research or ICMR guidelines.

v) Compliance with relevant regulations for Bio-medical and Health Research.

vi) Compliance to Good Clinical Practice Guidelines.

vii) Compliance to National Ethical Guidelines for Bio-medical and Health Research on Human Participation published by ICMR.

viii) Compliance with any other relevant regulations in force.

ix) AYUSH registered practitioner/expert should be part of the study team at each site.

5. It would be mandatory to the institution/organization to appraise the Ministry of AYUSH, Govt. of India about the research developments as per research timeline and the outcome.

21/4

(P.N. Ranjit Kumar)
[Joint Secretary to the Government of India]

To,

The Manager,
Government of India Press,
New Delhi