



केन्द्रीय आयुर्वेदीय विज्ञान अनुसंधान परिषद्

आयुष मन्त्रालय, भारत सरकार
जवाहर लाल नेहरू भारतीय चिकित्सा एवं होम्योपैथी अनुसंधान भवन
61-65, सांस्थानिक क्षेत्र, सम्मुख 'डी' ब्लॉक, जनकपुरी, नई दिल्ली-110058

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES

Ministry of AYUSH, Govt. of India

Jawahar Lal Nehru Bhartiya Chikitsa Evam Homoeopathy Anusandhan Bhawan
61-65, Institutional Area, Opp. 'D' Block, Janakpuri, New Delhi-110058

ग्राम : आयुष
Gram : "AYUSH"
Fax : 28520748
EPBX
28525852, 28520501
28522524, 28525831
28525862, 28525883
28525897

F. No. 87-1/2020-CCRAS/Tech./Hq. | 117

Date: 14.05. 2020
14 MAY 2020

ORDER

Sub: Constitution of Data and Safety Monitoring Board (DSMB) for monitoring of clinical trials and population based prophylactic studies of AYUSH interventions related to COVID 19.

In supersession to earlier orders of even no. dated 12.05.2020 and 13.05.2020, approval of competent authority is hereby conveyed for setting up of a Data and Safety Monitoring Board (DSMB) for monitoring of clinical trials and population based prophylactic studies of AYUSH interventions related to COVID 19 with following composition:

1. **Dr. Nandini K. Kumar** : **Chairperson**
Former Deputy Director General Senior Grade, Indian Council of Medical Research (ICMR)
2. **Dr. Prof. Padma** : **Member (Medical expert)**
Dept of Neurology, AIIMS
3. **Dr. M. S. Baghel** : **Member (Ayurveda expert)**
Former Director, IPGT&RA, Jamnagar
4. **Dr Nirmala Rege** : **Member (Clinical pharmacologist)**
Professor and head at Seth GS Medical college and KEM Hospital
5. **Dr. Madan Godbole** : **Member**
Processor, Endocrinology and Molecular Medicine, SGPGI, Lucknow
6. **Dr. Vishnu Vardhan Rao** : **Member (Statistics expert)**
Director, National Institute of Medical Statistics, ICMR, New Delhi
7. **Dr. Galib**, Associate Prof., AIIA : **Member (Pharmaco-vigilance)**
8. **Dr. B C S Rao**, Assistant Director (Ay.) CCRAS: **Member Secretary**

2. **The Terms of References (ToRs) of DSMB are as follows**

1. The duration of DSMB is for 2 years from the date of its constitution or completion of all trials related with COVID 19 for which the board is constituted
2. The board is independent from all other committees related to the studies for COVID 19 under AYUSH including Institutional Ethical Committee and all members should be devoid of any conflict of interest.
3. The board will maintain the confidentiality of its internal discussions and activities as well as contents of report provided to it.
4. The board should also assess the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the study sites, and other factors that can affect study outcome.
5. The meeting may be conveyed at Ministry of AYUSH or through video conferencing as appropriate.

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6. The sponsor or research team will take part in the meeting only if DSMB desire for specific issue for the particular discussion only
 7. The minimum number member required to compose a quorum is 50% of total strength
 8. The recommendations of DSMB are communicated to the sponsor, the sponsor should notify study sites and ensure recommendations are acted upon by the study centres.
3. CCRAS will act as Secretariat and extend all secretarial and logistic support for conducting the meeting from time to time. All the expenditure towards convening these meetings will be borne by CCRAS as appropriate. TA/DA and a remuneration of Rs 5000/- admissible as sitting fee for this purpose to the members as per admissible rules.

To,

Chairperson and members of the committee

S.K. Panigrahi
14-05-2020
(S.K. Panigrahi)

Admin Officer (P&B)
For Director General

Authority: Communication from Ministry of AYUSH (email dated: 12th May 2020 from Ministry of AYUSH)

Copy to:

1. Prof. Bhushan Patwardhan, Chairman, Interdisciplinary AYUSH Research and Development Task Force and Vice Chairman, University Grant Commission for information.
2. Dr JLN Sastry, CEO NMPB and Member Secretary, Interdisciplinary AYUSH Research and Development Task Force for information.
3. Dr. Arvind Chopra, Chief Clinical Coordinator, Centre for Rheumatic Diseases (CRD), Hermes Elegance, Convent Street Campus, Pune-411001 for information.
4. DGs of Research Councils, Directors of National Institutes, Director AIIA, Director IPGT&RA, Jamnagar for providing relevant information on clinical trials and other studies undertaken by them.
5. Dr. A Raghu, Joint Advisor, Ministry of AYUSH, Govt. of India, INA New Delhi for information.
6. Director (Institute), CARICD, Punjabi Bagh, New Delhi for information and with request that a copy of DSMB report may be forwarded to the Central Ethics Committee for further circulation to concerned Ethics Committees.
7. PPS to Secretary, Ministry of AYUSH, Govt. of India, INA New Delhi for information.
8. PPS to AS, Ministry of AYUSH, Govt. of India, INA New Delhi for information.
9. PPS to DG, CCRAS, PS to DDG, CCRAS, PS to DDA, CCRAS for information.
10. Dr S N Gaidhani, AD (P'ology), CCRAS to coordinate and liaison the matter with the support of statistical section.
11. Administrative Officer (Account), CCRAS for necessary action.
12. F.No. 3-35/2020-CCRAS/Admn./IMR for record and to forward the copy of DSMB report to the Central Ethics Committee. Further, copy of all communications related to COVID 19 clinical studies may be endorsed to Dr. Arvind Chopra (cdp5624@gmail.com).

cdp

S.K. Panigrahi
14-05-2020
For Director General