राष्ट्रीय होम्योपैथी आयोग

National Commission for Homoeopathy

JLN Bhartiya Chikitsa Avum Homoeopathy Anusandhan Bhavan
No.61-65, Institutional Area, Opp. 'D' Block, Janakpuri, New Delhi-110058
Phone: 011-28522906 Email: nchindia21@gmail.com Website www.nch.org.i

File No. 3-35/2023/Commission/HEB/Research/ 1388- 1398 **Date:** 15 MAY 2023

To,

1. The Principal Secretary/Secretary, (Department of AYUSH / ISM&H / Medical Education/ Health & FW – All State & U.T.
2. The Commissioner/Director of AYUSH / ISM&H- All State & U.T.
3. The Registrar of University (Including Deemed University) having affiliated/Constituent Homoeopathic Medical Colleges – All State & U.T.
4. The Registrar, Homoeopathic Board/ Council – All State & U.T.
5. The Principal of all the Homoeopathic Medical Colleges and Hospital (including Director, N.I.H. Kolkata & NEIAH, Shillong).
6. All Homoeopathic Associations and Federations/Society.
7. All other Stake Holders/General Public.

Sub: Comments/ Suggestions over the draft regulations namely 'National Commission for Homoeopathy (Medical Research in Homoeopathy), Regulations- 2023'- Reg.

Madam/Sir,

I am directed by the Competent Authority to circulate the draft Regulation 'National Commission for Homoeopathy (Medical Research in Homoeopathy), Regulations- 2023' regarding conduct of business of Commission, through website of the commission (www.nch.org.in) for seeking comments/suggestions over the draft regulation within period of 30 days w.e.f. 15.05.2023 as per the Rule 23 sub-section (d) of G.S.R. 772 (E) Ministry of Ayush notification dated 18.12.2020.

The comments/suggestions be sent on email: heb.nch@gmail.com, nchindia21@gmail.com.

Yours faithfully,

(Prof. Dr. Sanjay Gupta)
Secretary

Enclosed as above.

Copy to: -

1. The Secretary, Ministry of Ayush, B Block, GPO Complex, INA, New Delhi-110023.
2. Chairperson, National Commission for Homoeopathy, 61-65, Institutional Area, Janakpuri, New Delhi-110058.
3. IT Consultant with the direction to upload on website.
4. Guard File.

(Prof. Dr. Sanjay Gupta)
Secretary

National Commission for Homoeopathy

Notification

New Delhi, the May 2023

F.No. 3-35/2023/Commission/HEB/Research– in exercise of the powers conferred upon by section (10), sub-section (1) of clause (b) of the National Commission for Homoeopathy Act, 2020 (15 of 2020), the Commission hereby makes the following regulations, namely: -

1. Short Title and Commencement

(i) These regulations may be called the National Commission for Homoeopathy (medical research in Homoeopathy) Regulations-2023.

(ii) They shall come into force on the date of their publication in the official gazette.

2. Definitions

(a) "Clinical study" means research according to a protocol involving one or more human participants to evaluate biomedical or health-related outcomes, including interventional studies and observational studies in which the investigator does not assign human participants to interventions but observes them who have been given interventions in the course of routine clinical care, and may also include retrospective reviews of patient medical records or relevant literature.

(b) "clinical trial" means any systematic study of existing or new Homoeopathy drug, investigational new drug, in human participants to generate data for discovering or verifying its clinical, pharmacological, including pharmacodynamics or pharmacokinetic, or adverse effects with the objective of determining safety, efficacy or tolerance of the drug;

(c) "Ethics Committee" means the Ethics Committee constituted as per Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research and Good Clinical Practice Guidelines for Clinical Trials in Homoeopathy published by Central Council for Research in Homoeopathy, Ministry of Ayush, Govt of India.

(d) " Homoeopathic drug" includes " any drug intended for internal or external use for or in diagnosis, treatment, mitigation or prevention of diseases or disorder in human beings and animals; which is recorded in Homoeopathic proving or therapeutic efficacy of which has been established through clinical experience or research and as described in authoritative Homoeopathic literature as may be specified from time to time by the Central Govt. by notification; which is manufactured in accordance with techniques of Homoeopathic pharmacy and covers combination of ingredients of such Homoeopathic medicines, but does not include a medicine which is administered by injectable route".

15/5/23

(e) "investigational new drug in Homoeopathy" means new drug as defined under 'k' below and whose standards are drawn and which is under investigation in a pre-clinical or clinical trial regarding its safety, tolerance and efficacy;

(f) "investigator" means a person who is responsible for conducting clinical trial or clinical investigation at site;

(g) "new drug" means-

(i) a drug not specified in the respective authoritative books of Homoeopathy as notified by Central Govt. and prepared by using such modern advances; with respective therapeutic claims in human beings or animals.

(ii) a drug, single or in combination of pharmacopeial Homoeopathic drugs, intended for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form;

(h) "Principal Investigator" means the investigator who has the responsibilities to coordinate between the different Investigators involved in a study at one site or different sites in case of a multi-center study.

(i) "Protocol" means a document that states the background, rationale, objective(s), design, methodology, statistical considerations and organization of the trial and the conditions under which it is to be performed and managed. A list of items to be included in a homoeopathic clinical research protocol is compiled in a subsequent chapter. The content and format of the protocol should take into consideration the relevant regulatory requirements and the guiding principles for the trial. The term protocol, unless otherwise specified, relates to the latest amended version of the document, read in conjunction with all its appendices and enclosures.

(j) "research organisation" means a person or an organisation to whom a sponsor may transfer or delegate one or more of its functions and duties regarding conduct of research study.

(k) The words and expressions used herein and not defined but defined in the Act or in the guidelines mentioned herein this regulation shall have the same meanings as respectively assigned to them in the Act or guidelines.

3. Scope

All types of researches for better academic understanding; for the advancement of Homoeopathy on scientific lines; interventional or non-interventional; fundamental or basic research, experimental, preclinical and clinical trials; of different phases; with one or more pre-specified outcome measures; includes studies of interdisciplinary in nature as well as of integrative approach.

4. Guidelines, Rules to be followed for undertaking research in Homoeopathy:

All investigators, research organizations are expected to follow following guidelines for ethical and scientific reasons some of which are mandatory as per notification:

15/5/17

a) All clinical trials relating to Homoeopathy (homoeopathic clinical trials) must be conducted in accordance with the Good Clinical practices of Homoeopathy (GCP-Homoeopathy).
b) Additionally, they should not be in contravention to any of the international or national regulatory guidelines for bio-medical research including but not limited to Drugs and Cosmetics Act (1940), and Rules (1945) (including Schedule Y), and applicable amendments thereafter.
c) Declaration of Helsinki (2013 or later versions, as applicable),
d) Good Clinical Practices Guidelines of the Ministry of Health & Family Welfare, Government of India (2001 or later versions, as applicable),
e) National Guidelines for Biomedical and Health Research Involving Human Participants (2017 or later versions as applicable),
f) National Ethical Guidelines for Biomedical Research Involving Children (2017 or later versions as applicable)
g) ICMR Policy on Research Integrity and Publication Ethics (2019 or later versions as applicable), and other relevant regulations and guidelines, wherever applicable.
h) For animal experiments, Rules and guidelines as notified by Committee for the Purpose of Control and Supervision of Experiments on Animals, Govt of India are to be followed.

5. Responsible party

The sponsor of an applicable trial will be considered the responsible party, unless and until the sponsor designates a qualified principal investigator of such trial if so, designated by a sponsor, grantee, contractor, or awardee as the responsible party.

6. Registration

All interventional clinical trials/studies shall be registered by the responsible party with Clinical Trial Registry of India (CTRI) before the enrolment of the first participant in the specific clinical trial.

7. Submission of research records

Commission has the power to call for all the information and documents, on online platform or in the form and manner as specified, from the responsible party related to research trial for assessment of regulatory compliances and for any violations including details of financial resources for the project. Responsible party shall submit an affidavit stating that submitted clinical trial information is false or misleading.

8. Research Audit

Commission can authorise a team of experts or through third party agency for the Research audit of the trial at anytime during of after the trial for which responsible

15/5/23

party shall cooperate fully and provide logistic support as may be required by the auditors.

9. **Publication of research in peer reviewed journals:** It is advised that authors should publish their articles in non-predatory peer reviewed journals.

10. **Misconduct of research**

i. Research misconduct is defined as:

a. Fabrication, falsification, plagiarism, self-plagiarism, or deception in proposing, carrying out or reporting results of research.
b. Deliberate, dangerous or negligent deviations from accepted practices in carrying out research.
c. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others.
d. It also includes intentional, unauthorized use, disclosure or removal of, or damage to, research-related property of another, including apparatus, materials, writings, data, hardware or software or any other substances or devices used in or produced by the conduct of research.

ii. Responsibilities of the organization conducting research:

a. It is the responsibility of the organisation to investigate all allegations of research misconduct made against its research team in an unprejudiced manner. Findings of research misconduct would be matters for consideration under the Institutional ethics committee. The onus of disciplinary action lies on the institutional head based on the recommendations of the IEC, a copy of which should be essentially sent to the sponsor, Commission and other associated or regulatory bodies in the research.
b. The organization should define responsibilities of each participant in research at every level.
c. The outcome of any investigations on research misconduct / non - compliance or violation of mandatory guidelines, should be essentially conveyed to the sponsor, Commission and other associated bodies in the research.
d. Commission research regulation clearly states that research misconduct is taken seriously in the organisation and that any member of staff raising bona fide concerns can do so confidentially, and without fear of suffering any detriment, as also that malafide allegations will invite disciplinary action.

iii. Organisation's guidelines for investigating allegations of research misconduct or non-compliance of regulatory guidelines:

15/5/23

a. Each organisation must have in place formal written procedures for dealing with allegations of research misconduct against its staff and students and other researchers.
b. If required, legal advice may be sought.
c. Advise of Commission may be sought on the decision of the organization.
d. Declaration of independent and impartial investigation should be issued in each enquiry.
e. Confidentiality should be strictly maintained.
f. All interested parties should be informed of the allegation at an appropriate stage in the proceedings.
g. Anyone accused of misconduct should have the right to respond
h. The allegation should be dealt with in a fair and timely manner. Proper records of the proceedings should be kept.
i. The outcome should be made known as quickly as possible to all interested parties.
j. Anyone found guilty of misconduct should have the right to appeal.
k. Appropriate sanctions and disciplinary procedures should be in place for cases when the allegation is upheld.
l. If appropriate, efforts should be made to restore the reputation of the organization and/or accused party if the allegation is dismissed.

iv. Responsibilities of the Commission
a. In case of direct appeal to Commission, the enquiry will be rerouted to the organization.
b. Commission may wish to undertake the enquiry at its level, depending on the nature of allegations. The organizational support for the same will be mandatory.

v. Sanctions and/or disciplinary actions in proven research misconduct / non-compliance or violation of mandatory guidelines, shall be in proportion to the findings which may be as under on case to case basis:
a. Warning
b. Reprimand letter
c. Penalties
d. Withdrawal of grant
e. Withdrawal of publications etc
f. Guidelines for future monitoring
g. Legal action, as per expert advise

15/5/13

11. Homoeopathic Research Regulation Committee:

A. The committee shall be constituted by the Commission as per the following composition:

i) Advisor (Homoeopathy Ministry of Ayush– Chairman
ii) Director General CCRH – Member
iii) Two experts from homoeopathy with a minimum of 20 years of research experience in homoeopathy in a recognized organization/ institute of the Government of India
iv) One expert Bioethicist – Member
v) One expert in Bio-statistics with a minimum of 20 years of professional experience in biomedical research institution – Member
vi) One expert from Basic sciences/Pharmacy/ Biotechnology/Modern Medicine/Public Health with a minimum of 20 years of professional experience in biomedical research – Member
vii) One pharmacologist with a minimum of 20 years of professional experience in pharmacological research - Member
viii) President – Homoeopathy Education Board – Convenor

The Committee may, if necessary, with prior approval of the Chairman, Commission co-opt member(s) or invite Government / Non-Government expert(s) for dealing with any specific issue and problem relating to different subjects such as legal, intellectual property, basic sciences, genetics, etc. to seek their advice.

B. Terms of reference:

i) The term of committee shall be three years from the date of constitution.
ii) The committee shall meet at least once a year. The committee shall meet more frequently depending upon the applications submitted for consideration as per the directions of the Chairperson. Travelling allowance and sitting fee for the committee members shall be borne by the Commission.
iii) The Commission will draw the standard operating procedures for the committee detailing the issues of conflicts of interest, non-disclosure of deliberations and codes of conduct for the members.
iv) The committee shall work on the agenda drawn by the homoeopathy education board.
v) The committee shall draw guidelines on specific issues as referred to it from time to time, for homoeopathic research, ensuring superior performance in terms of quantity, consistency, collaboration, quality and other aspects of excellence and ensuring highest standards of ethics and participant protection.
vi) The committee shall have the power to appoint an arbitrator in a time bound manner to resolve conflicts between parties undertaking research, as per need of the case referred to it for consideration.
vii) The committee shall have the power to monitor a study progress for a definite time period as per need of the case referred to it for consideration.

15/5/23

viii) The committee shall give its recommendations on the research projects, referred to it by authorities, relating to violation of the mandatory guidelines issued by the government of India from time to time.

ix) The Committee shall deal with appeals of aggrieved party relating to research misconduct as referred by the Commission and shall submit report with recommendations to the Commission.

13. INTERPRETATION AND POWER TO RELAX

a. Where any doubt arises to the interpretation of these regulations, it shall be referred to the Commission for clarification

b. Where Commission is satisfied that the operation of any of these regulation causes undue hardship in any case, it may by order for the reasons recorded in writing, dispense or relax the regulation to such extent and subject to such exceptions and conditions as it may consider necessary for dealing with the case in a just and equitable manner.

(Dr. Sanjay Gupta)

Secretary, NCH

F.No._____