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॥ आयुषे सर्वलोकानाम् ॥

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Ref. No. Sec/NCISM/Regulations/2023-1 **Dated. : 04-08-2023**

PUBLIC NOTICE

Public opinion has been invited on the draft regulation namely:-

1 **The National Commission for Indian System of Medicine (Pre-Ayurveda Program (PAP)for Bachelor of Ayurvedic Medicine and Surgery (BAMS) Regulations-2023**
2 **The National Commission for Indian System of Medicine (Medical research in Indian system of medicine) Regulations, 2023.**
3 **The National Commission for Indian System of Medicine (Establishment of ASUS Colleges outside Indian by the Indian Universities independently or in collaboration with the universities/Institutes/NGO recognised by the competent authority of country outside Indian & seeking degree recognition from NCISM) Regulations 2023.**

The opinions may reach NCISM office through E-mail ID secretary@ncismindia.org within 30 days of this announcement.

Prof. (Dr.) B.L. Mehra
Secretary (NCISM)
सचिव
भारतीय चिकित्सा पद्धति राष्ट्रीय आयोग
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Copy to:-

1 The Chairman, National Commission for Indian System of Medicine, New Delhi-110058.
2 The Secretary, Govt. of India, Ministry of AYUSH, GPO Complex, INA, New Delhi-110023.
3 All Board Presidents of NCISM
4 All Commission Members of NCISM
5 Guard file.

Prof. (Dr.) B.L. Mehra
Secretary (NCISM)

National Commission for Indian System of Medicine
NCISM Regulation, 2023

Notification…

F. No…/Commission/regulation/2023- In exercise of the powers conferred upon by section (10), sub- section (1) of clause (b) of the National Commission for Indian System of Medicine Act, 2020 14 of 2020, the Commission here by makes the following regulations, Namely **–**

1. **Shot Title and Commencement**. –
   (i) These regulations may be called **National Commission for Indian System of Medicine (Medical research in Indian system of medicine) regulation, 2023.**
   (ii) They shall come into force from the date of publication in the official gazette:
1. **Purpose of the regulation**: - Purpose of this regulation is to inculcate research aptitude among the students as well as the teachers and practitioners and also to nurture curiosity and questioning and to lay down policies for regulating medical researchers in teaching institution of Indian medicine including teaching hospitals and the research conducted by the private practitioners in the private hospitals. The research conducted by the Central Councils for Research in Indian System of medicine shall not come under this regulation.
2. **Definitions**. -

   (a) "Research" in Indian System of medicine means a scientific approach of answering research questions, solving a problem, or generating new knowledge through a systematic experimentation and/or orderly collection of ancient literature, organisation and analysis of information with an ultimate goal of making the research useful for the society at large.

   Explanation. -Here "research" includes all types of researches for better academic understanding, for the advancement of Indian System of Medicine on scientific lines, interventional or non-interventional studies; fundamental or basic research, experimental, preclinical and clinical trial' of different phases; with one or more pre-specified outcomes measures; includes studies of interdisciplinary in nature as well as of integrative approach. Research also includes literary research regarding ancient text,

menu scripts of related to Indian System of Medicine and other relevant Indian sciences.

(b) "Research ethics" meansan ethics that addresses the questions, dilemmas and issues related to the ethical conduct of scientific research.

(c) "Clinical trial" means any systematic studies of existing or new Ayurveda/ Unani/ Siddha/ sowa-rigpa research, investigational new drug in human participants to generate data for discovering or verifying its clinical, pharmacological, including pharmacodynamics or pharmacokinetic properties, or adverse effects with the objective of determining safety, efficacy or tolerance of the drug.

(d) "Clinical study" means research according to protocol involving one or more human participants to evaluate bio medical 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 innervations in the course of routine clinical care, and may also include retrospective reviews of patient medical record or relevant literature.

(e) "Drug" means an Ayurveda/Unani/Siddha/ Sowa-rigpa drug as per the definition given in the Drug and Cosmetic act.

(f) "New drug" means: -

i. A drug not specified in the authoritative books of Indian System of Medicine as notified by Central Government and prepared by using such modern advances.' with respective therapeutic clams in human being or animal.

ii. "A drug" a single or in combination of pharmacopeia Ayurveda/Unani/ Siddha/ Sowa- rigpa drug intended for certain claims and proposed to be marketed with modifies or new claimsincluding indication, roots of administration, doses and dosed form.

(g) "Protocol" means a document containing background, objective, rationale, design, methodology including performance, management, adverse event and organisation of the trial and the conditions under which it is to be performed and managed.

(h) "Research Organisation" means a person or an organisation to whom sponsors may transfer or delegate one or more of its function and duties regarding conduct of research study.

(i) "Ethics committee" means the ethics committee constituted as per ethical guidelines for bio medical research on human subject issued by any Research Council of Indian System of Medicine or ICMR.

(j) "Principal Investigator" means the investigator who have the responsibilities to co-ordinate between the different investigators involve in a study at one site or different sites in case of multi-centre study.

(k) "Research organisation" means a person or an organisation/hospital to whom a sponsormay transfer or delegate one or more its functions and duties regarding conduct of research study.

(l) "Misconduct of research" means;

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. Failure to follow established protocols if this failure results in unreasonable risk or harm to humans or the environment and facilitate misconduct in research by collusion in, or concealment of, such actions by others;

d. 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 substance(s) or device(s) used in or produced by the conduct of research;

(m) "Indian System of Medicine" means Ayurveda, Unani, Siddha, Sowa-rigpa systems of medicine.

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

3. **General Consideration. -** General consideration for conducting research for Indian System of Medicine.

While conducting the research all stake holders are expected to follow the following guidelines for ethical and scientific reasons.

a) All clinical trials related to Indian System of Medicine must be conducted in accordance with the good clinical practice guidelines issued by relevant research councils of Indian System of Medicine.

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 cosmetic act (1940), and rules (1943) (including schedule Y), and applicable amendments thereafter;

c) Declaration of Helsinki (2012 or later versions, as applicable);

d) Good Clinical Practice guidelines of the Ministry of Health & Family Welfare, Government of India (2001 or later versions, as applicable);

e) National Guidelines for Biomedical and Heath 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, rule and guidelines as notified by the Committee for the Purpose of Control and supervision of Experiments on Animal (CPCSEA), Government of India are tobe followed.

4. **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.

5. **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 violation(s) including details of financial resources for the project. Responsible party shall submit an affidavit stating that submitted clinical trial information is not false or misleading.

6. Publication of research outcomes in peer-reviewed-journals:

It is advised that the researchers' authors should publish their studies in non- predatory peer reviewed journals.

7. Patent-

It is advised that the researcher may go for patenting his innovation in place of publication if deemed fit by the researcher.

8. Research Audit: -

Commission may authorise a team of experts or third party agency for the research audit of the trial at any time during or after the trial for which responsible party shall cooperate fully and provide logistic support as may be required by the auditors.

9. 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.

10. Misconduct of research: -

i. Responsibilities of the organization conducting research:

a) It is the responsibility of the research 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 (IC). The onus of disciplinary action lies on the institutional Head based on the recommendations of the IC, a copy of which should be essentially sent to the sponsor, Commission and other associated or regulatory bodies in the field of research:

b) The organization should define responsibilities of each research participant in research at every level;

c) The outcome of any investigation(s) 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's research regulations clearly state 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.

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

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. Advice 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(s) at an appropriate stage in the proceedings;

g. Anyone accused of misconduct should have the right to respond h.

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;

iii. Responsibilities of the Commission: -

a) In case of direct appeal to Commission, the enquiry will be re-routed to the organization.

b) Commission may wish to undertake the enquiry at its level, depending on the nature of allegation(s). The organizational support for the same will be mandatory.

iv. Sanctions and/or disciplinary actions in proven research misconduct / noncompliance 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. Penalty

d. Withdrawal of grant

e. Withdrawal of publications etc.

f. Guidelines for future monitoring

g. Legal action, as per expert advice

11.Research monitoring committee for Indian System of Medicine: -

A. The committee shall be constituted by the Commission to monitor the research activities in the field as mentions in the definition. The committee shall work on the agenda drown by the Board of Ayurveda and Board of Unani Siddha and Sowa –rigpa

I. Constitution of the committee:

The Commission shall constitute a committee to monitor the research as per the following composition.

a) President, Board of Ayurveda – Chairman

b) President Board of Unani Siddha and Sowa- Rigpa -

Co-Chairman

c) Director General, CCRAS – Member

d) Director General, CCRUN- Member

e) Director General, CCRAS

f) One expert from basic science.

The Committee may, if necessary, with prior approval of the Chairman, Commission co-opt member(s) or invite Government / Non-Government experts) 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 the 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 draw guidelines on specific issues as referred to it from time to time, for Indian System of Medicine research, ensuring high quality performance in terms of quantity, consistency, collaboration, quality and other aspects of excellence and ensuring highest standards of ethics and participant protection in the research domain.

v. 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.

vi. 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.

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

viii. 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.

12. **Funding for Research & Publication-**

NCISM may by signing MOU with the research Councils, Industry, NGO may generate fund for research or Publication.

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. B.L Mehra
Secretary I/C, NCISM

F. No.----------