INDIAN COUNCIL OF MEDICAL RESEARCH

ETHICAL REQUIREMENTS

FOR

RESEARCH IN INTEGRATIVE MEDICINE

An Addendum to

ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

MARCH 2025

Suggested Citation:

Ethical Requirements for Research in Integrative Medicine - an Addendum to ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, ICMR, March 2025.

ETHICAL REQUIREMENTS FOR RESEARCH IN INTEGRATIVE MEDICINE

In this document, Research in Integrative Medicine (RIM) refers to research involving multimodal interventions, wherein one or more Ayush[a] practices, approaches, or modalities are integrated alongside those of modern/ conventional[b] medicine to address the health needs of individual(s).

SCOPE:

The ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, in Section 7.13 discussed 'Clinical trials on traditional systems of medicine'. An addendum is being made to this Guideline to facilitate and guide Research in Integrative Medicine involving human participants, by researchers in modern medicine institutions.

Recommendations:

1. For undertaking an ethics review of proposed Research in Integrative Medicine, the Ethics Committee (EC) shall invite two subject matter experts to the EC meeting from the relevant Ayush system(s). These Ayush experts need not be permanent members of the EC but may be co-opted when there are integrative medicine research proposals under review. They will be considered part of the EC quorum for decision-making. Like other expert members of the EC, these experts must not have any conflicts of interest related to the study under consideration. Additionally, at least one of these experts must be external to the institution. The EC should be duly registered with the Department of Health Research (DHR) and may also be registered with the Central Drugs Standard Control Organization (CDSCO) if it reviews clinical trials as defined under the Drugs & Cosmetics Act, the New Drugs & Clinical Trial Rules, 2019 or other relevant regulations. For multicentre research, a common ethics review may be conducted by the designated EC.
2. Informed Consent should be tailored to ensure that participants fully understand the nature of the research in integrative medicine. All relevant ethical considerations and guidelines for biomedical and clinical research involving humans in India shall also apply to integrative research.
3. If the medicinal product or modalities approved for use in clinical Ayush practice (Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa, Homoeopathy) is being used for Research in Integrative medicine, it will not require additional evidence of safety (from animal studies or phase I/II human clinical trials).[c]
4. Research involving non-codified traditional medicines must go through the entire prescribed regulatory approval processes as per applicable rules/regulations/guidelines and any amendments thereto [c].

xxxxxxxxxxxxxxxx

Notes

a. *In India, Ayush is the officially codified traditional medical practice including Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa and Homoeopathy, which are recognized under the National Commission for Indian System of Medicine (NCISM) Act for Ayurveda, Siddha, Sow-Rigpa, Unani; and National Commission for Homoeopathy (NCH) Act for Homoeopathy by the Government of India.*
b. *Often referred to by other terms as well*
c. *Includes relevant provisions in the Drugs and Cosmetics Act, 1940 & Rules thereunder and New Drugs and Clinical Trial Rules (2019), Good Clinical Practice guidelines for clinical trials in Ayurveda, Siddha and Unani (ASU-GCP), General Guidelines for Clinical Evaluation of Ayurvedic Interventions (2018), Good Clinical Practice Guidelines for Clinical Trials in Homoeopathy (2021), and other relevant rules/ regulations/ guidelines and their revisions from time-to-time.*

References

1. ICMR. Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 [cited 2025 Feb 18]. Available from: https://ethics.ncdirindia.org//asset/pdf/ICMR_National_Ethical_Guidelines.pdf
2. DHR. National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) | Department of Health Research, MoHFW, Government of India. Available from: https://dhr.gov.in/national-ethics-committee-registry-biomedical-and-health-research-necrbhr
3. CDSCO. "SUGAM Portal." Cdscoonline.gov.in, [cited 2025 Feb 21]. Available from: https://cdscoonline.gov.in/CDSCO/homepage
4. The New Drugs and Clinical Trials Rules 2019 [cited 2025 Feb 18]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=OTg4OA.
5. Good Clinical Practice Guidelines for clinical trials in Ayurveda, Siddha and Unani (ASU-GCP) Department of Ayush, Ministry of Health and Family Welfare, 2013 [cited 2025 March 3]. Available from: https://e-aushadhi.gov.in/ayush/download/external/Notification/Good_clinical_practice201902121952.pdf