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# ICMR publishes addendum to ethical requirements for research in integrative medicine

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**A significant step in encouraging the scientific community to explore Integrative Medicine**

The Indian Council of Medical Research (ICMR) has published an addendum to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017) to provide a structured ethical framework for Research in Integrative Medicine (RIM).

Secretary, Ministry of Ayush, Vaidya Rajesh Kotecha highlighted the significance of the development and said, “The addition of these ethical guidelines marks a significant step in encouraging the scientific community to explore Integrative Medicine with greater credibility and confidence. By providing a structured ethical framework, we aim to inspire researchers to advance evidence-based integration of traditional and modern medicine, ensuring safe, effective, and scientifically validated healthcare solutions for all".

Integrative Medicine (IM) involves a multimodal approach where Ayush systems are integrated alongside modern/conventional medicine to enhance patient care and improve health outcomes.

This addendum aims to guide researchers, institutions, Ethics Committees (ECs), and regulatory bodies involved in Integrative Medicine research, ensuring that scientific integrity and patient safety remain paramount.

The addendum introduces key measures to enhance the ethical and regulatory framework for Integrative Medicine research. Ethics Committees overseeing such research must now include two Ayush subject-matter experts, with at least one being external to the institution, ensuring well-rounded and informed deliberations.

Informed consent standards have been strengthened, requiring that research participants receive clear, tailored information about Integrative Medicine interventions while adhering to India's standard ethical guidelines for biomedical and clinical research.

Additionally, Ayush-approved medicines used in integrative research will not require extra safety trials or preclinical studies. However, non-codified traditional medicines must undergo the entire regulatory approval process. To ensure compliance, all research must align with the Drugs & Cosmetics Act (1940), New Drugs & Clinical Trial Rules (2019), and Good Clinical Practice (GCP) guidelines specific to Ayush systems.