



ICMR Bioethics Unit

INDIAN COUNCIL OF MEDICAL RESEARCH

**ETHICAL REQUIREMENTS
FOR
SYSTEMATIC REVIEW & META-ANALYSIS
PROPOSALS**

An Addendum to

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

JANUARY 2024

Ethical Requirements for Submission of Systematic Review and Meta-Analysis Proposals

1. A systematic review refers to the review of available evidence on a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant primary research in the form of published articles and to extract and analyse data from such published studies that are included in the reviews. Meta-analysis involves statistical synthesis or quantitative methods of combining the evidence from individual studies and it may or may not be part of a systematic review.
2. Systematic reviews/ meta-analyses generally use published/unpublished studies, which are publicly available. These are usually aggregated data from individual studies that do not include identifiable details of study participants. A meta-analysis that uses individual participant data (IPD), access data on request from researchers conducting the original studies that are anonymized and de-identified and are available in the public domain, published or unpublished.
3. There are standard guidelines for the preparation of systematic review protocols such as PRISMA-P 2015 guidelines. There are databases that register systematic review protocols prospectively, like Cochrane (<https://www.cochrane.org/>), PROSPERO (<https://www.crd.york.ac.uk/prospéro/>), Registry of Systematic Reviews/ Meta-Analyses (<https://www.researchregistry.com/>), INPLASY (<https://inplasy.com/>), or other generic registers that are open to registration like Open Science Framework (OSF) Registries and protocols.
4. Systematic reviews are commonly employed to assess the efficacy of drug treatments versus placebos or alternatives, but they also extend to diverse areas such as surgical techniques, diagnostic test accuracy, psychosocial interventions, public health strategies, examination of adverse effects, prevalence/ incidence assessments, economic evaluations, and other such areas. They provide a synthesis of available evidence for healthcare practitioners, to develop clinical guidelines, for policy-makers to inform policy discussion and analysis, and to prioritize areas for further research.

Recommendations:

The ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, mandated the submission of all types of research, including systematic reviews, to the Ethics Committee for review or to seek an exemption from ethics review. To this an addendum is being made as below:

If a systematic review/ meta-analysis protocol has followed standard guidelines and procedures including prospective registration in a standard database/ registry (see Annexure I), it does not require submission to the ethics committee for clearance.

Annexure I

S N	Guidance documents	
1.	National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. ICMR; 2017	https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf
2.	Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews. 2015;4(1)	https://doi.org/10.1186/2046-4053-4-1
3.	The Prisma 2020 statement: An updated guideline for reporting systematic reviews. PLOS Medicine. 2021;18(3)	https://doi.org/10.1371/journal.pmed.1003583
4.	Cochrane Handbook for Systematic Reviews of Interventions version 6.4 (updated August 2023)	https://training.cochrane.org/handbook
Databases for protocol registration		
5.	protocols.io.	https://www.protocols.io/
6.	Centre for Open Science Preregistration	https://www.cos.io/initiatives/prereg
7.	Cochrane	https://www.cochrane.org/
8.	INPLASY	https://inplasy.com/
9.	PROSPERO - International prospective register of systematic reviews.	https://www.crd.york.ac.uk/PROSPERO/
10.	Research registry	https://www.researchregistry.com/

Suggested Readings:

1. Beginner's guide for systematic reviews: a step-by-step guide to conduct systematic reviews and meta-analysis. Indian Council of Medical Research. 2022. Available from: https://main.icmr.nic.in/sites/default/files/upload_documents/BEGINNERS_GUIDE_FINAL_BOOK.pdf (Accessed 17 Jan 2024).
2. Bring structure to your research. protocols.io [Internet]. Available from: <https://www.protocols.io/> (Accessed 17 Jan 2024).
3. Centre for Open Science Preregistration [Internet]. Available from: <https://www.cos.io/initiatives/prereg> (Accessed 17 Jan 2024).
4. Cochrane [Internet]. Available from: <https://www.cochrane.org/> (Accessed 17 Jan 2024).
5. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). Cochrane Handbook for Systematic Reviews of Interventions version 6.4 (updated August 2023). Cochrane, 2023. Available from: <https://training.cochrane.org/handbook> (Accessed 17 Jan 2024).
6. INPLASY [Internet]. Available from: <https://inplasy.com/> (Accessed 17 Jan 2024).
7. Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. Systematic Reviews. 2015;4(1). Available from: <https://doi.org/10.1186/2046-4053-4-1>
8. National Ethical Guidelines for Biomedical and Health Research involving Human Participants. New Delhi: Indian Council of Medical Research;2017. Available from: https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf (Accessed 17 Jan 2024).
9. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The Prisma 2020 statement: An updated guideline for reporting systematic reviews. PLOS Medicine. 2021;18(3). Available from: <https://doi.org/10.1371/journal.pmed.1003583>
10. PROSPERO International prospective register of systematic reviews [Internet]. Available from: <https://www.crd.york.ac.uk/PROSPERO/> (Accessed 17 Jan 2024).
11. Research registry [Internet]. Available from: <https://www.researchregistry.com/> (Accessed 17 Jan 2024).

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