Column: Tips on Research and Publication

REPORTING OF 'ETHICAL CONSIDERATIONS' IN RESEARCH PAPERS: THE ESSENTIALS

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ABSTRACT

Ethical considerations are a fundamental component of research manuscripts. Standard practices involve documenting written informed consent, ethics committee approval, and trial registration. When mentioning the ethics committee or trial registry details, include the name, approval number, and date. Providing clear and comprehensive documentation of ethical considerations fosters transparency and enhances trust in the research process among editors, reviewers, and readers.

Keywords: Ethics committee, Informed consent, Trial registry, Declaration of Helsinki

INTRODUCTION

Research involving human participants or animals must ensure the protection of rights, as outlined by the World Medical Association in the Declaration of Helsinki (WMA 2024) and the International Council for Harmonisation Good Clinical Practice (ICH-GCP) (https://www.ich.org/). All biomedical journals are required to publish studies that adhere to the highest ethical standards. Key ethical considerations include informed consent and an ethics committee (EC) approval. Trial registration is also recommended by the International Committee of Medical Journal Editors (ICMJE) for interventional studies.[1] ECs are responsible for overseeing the ethical aspects of research in accordance with the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017.[2] Journal editors follow the guidelines of the ICMJE (https://www.icmje.org/icmje-recommendations.pdf), which emphasize adherence to ethical principles. They are expected to reject studies that do not comply with these standards. Most journals, especially those that are its members, follow the guidelines of the Committee on Publication Ethics(COPE)(https://publicationethics.org/guidance?f%5B0%5D=type%3A21).

'Ethical Considerations' in the manuscript

These details are typically included under the "Methods" section, often in the first paragraph. In some cases, a separate subsection titled 'Ethical Considerations' is used to describe these aspects. Occasionally, it appears after the 'Statistical Analysis' subsection. Less commonly, some journals include additional subheadings for informed consent, ethics approval, and trial registration, either within

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the "Methods" section or, in some cases, after the "Discussion" section, similar to the "Acknowledgements" section, before the references.

Informed consent

For all research involving human participants, written informed consent must be obtained, with few exceptions. This process involves four key components: providing relevant information to eligible participants, ensuring that they have the capacity to understand the information, confirming that they have understood the information provided, and ensuring that participation is a voluntary decision. If participants lack the capacity to provide consent, informed consent must be obtained from a legally authorized representative (LAR), typically the spouse or family member who makes decisions on their behalf.[3] According to the ICMR guidelines, the consent process must be documented. Additionally, if the participant or LAR is illiterate, an impartial witness should be present during the consent process.

The fact that written informed consent was obtained from all research participants must be explicitly mentioned in the research manuscript. A typical statement would be:

"All participants provided written informed consent prior to their participation in the study."

A written informed consent statement is recommended for publishing case reports and case series while ensuring anonymity and confidentiality, and some journals mandate it.[4] Some studies, particularly drug trials, require *video* or *audio recording* of the consent process, as mandated by the Central Drugs Standard Control Organization (CDSCO). In certain situations, alternative forms of consent, such as *electronic consent* or *verbal consent*, may be used, provided that the rationale is clearly documented. These alternative forms of consent for research should also be approved by the respective ECs. For studies involving children, consent must be obtained from parents or a LAR. According to ICMR guidelines, *written assent* is recommended for children aged 13 to 17, while *oral assent* suffices for those aged 7 to 12. For children under 7, parental consent alone is deemed adequate. This must be clearly stated in the manuscript. For example:

"Participants provided written assent, and written informed consent was obtained from their parents."

Certain study designs, such as retrospective studies using data from clinical records, may not require participant consent. In such cases, permission is obtained to use the medical records from the competent authority (e.g., the medical superintendent of a hospital), and the EC grants a waiver of consent. Typically, permission details from the competent authority do not need to be included in the manuscript; however, a statement indicating a waiver of consent from the EC should be provided. Under the Mental Health Care Act 2017, for intervention studies, if a participant cannot provide free and informed consent but does not resist participation, approval must first be obtained from the State Mental Health Authority before seeking consent from a LAR.

Ethics committees

ECs of institutions or hospitals are referred to as *Institutional ECs* (IECs) or *Institutional Review Boards* (IRBs). Independent ECs (IECs (Ind)) exist in settings where IECs are unavailable. Approval from an EC is mandatory for all studies involving humans or animals, which must be explicitly stated in the manuscript. The manuscript should include the name of the ethics committee, the approval number, and the date of approval. For example:

"Approval was obtained from the Institutional Ethics Committee of XYZ Medical College (or

XYZ Hospital) (approval number XX, dated XX.YY. ZZ)."

However, for double anonymized peer review, the details may need to be masked in the submitted manuscript and provided separately in the cover letter. Some journals require two versions of the manuscript: one complete and another anonymized. These details are added to the final manuscript upon acceptance.

For multicentric studies, the EC of the principal investigator (PI) is considered as the designated EC, while the ECs of collaborators or site PIs serve as the participating center ECs. Typically, the coordinating PI obtains EC approval first, followed by the site PIs. The 2023 ICMR guidelines emphasize the importance of joint ethics reviews for multicentric studies to facilitate effective communication between ECs and ensure transparency in the research process (https://ethics.ncdirindia.org/icmr_ethical_guidelines.aspx).

Studies involving secondary data, such as publicly available datasets or systematic reviews of published literature, do not require EC approval. However, the primary studies, including those contributing to pooled data, must have obtained EC approval, and these details should be included in the submitted manuscript.

Similarly, publishing case reports and case series typically do not require EC approval, as informed consent is generally sufficient. However, definitions of case series and the need for EC approval can vary across centers. Therefore, in cases of uncertainty, it is advisable to seek EC approval. An EC waiver may be granted for certain study types, such as retrospective chart reviews. This can be mentioned as:

"An ethics waiver was obtained from the Institutional Ethics Committee of XYZ Medical College (or XYZ Hospital) for this study."

Since 2013, ECs overseeing clinical trials have been required to register under the CDSCO (www.cdsco.gov.in/). Additionally, from 2019, ECs overseeing clinical trials and biomedical and health research must also register under the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR) (www.naitik.gov.in/). Including details of ECs in the manuscript is important as it enables editors, reviewers, and readers to verify whether the EC is registered with the ICMR or equivalent bodies.

Although registration is mandatory, many ECs remain unregistered, raising concerns about their standards.[5] Further quality assurance can be achieved through accreditation. In India, the National Accreditation Board for Hospitals and Healthcare Providers (NABH) (https://nabh.co/) offers accreditation to ECs, whereas international accreditation is available through organizations such as the Association for the Accreditation of Human Research Protection Program (AAHRPP) (https://www.aahrpp.org/) and the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) (https://www.sidcer-fercap.org/pages/about-the-program.php).[6]

Trial registration

All clinical trials must be registered in a publicly accessible trial registry. *Prospective registration*—i.e. at or before patient enrollment—is required to ensure transparency in the study protocol and make any deviations apparent to editors, reviewers, and readers. Trials can be registered in one of the Primary Registries in the *WHO Registry Network* (https://www.who.int/clinical-trials-registry-platform/network/primary-registries) or an *ICMJE-approved registry* (https://www.icmje.org/about-

icmje/faqs/clinical-trials-registration/). Most journals require trial registration to be specified in submitted papers involving intervention studies.

In India, all clinical trials are required to be registered in the Clinical Trials Registry-India (CTRI)database(https://ctri.nic.in/Clinicaltrials/login.php), a free, online public record system established by the National Institute of Medical Statistics, ICMR. The CTRI is listed under the WHO Registry Network. To further improve transparency, ICMR guidelines also encourage (not mandatory) the registration of all study protocols for observational studies in the CTRI.

Several other countries maintain their own trial registries, such as ClinicalTrials.gov in the US (https://clinicaltrials.gov/), the ISRCTN registry in the UK (https://www.isrctn.com/), and the EU Clinical Trials Register (EU-CTR) (https://www.clinicaltrialsregister.eu/ctr-search/search). Additionally, the International Traditional Medicine Clinical Trial Registry (ITMCTR), operated by the China Center for Evidence-Based Traditional Chinese Medicine, is available (http://itmctr.ccebtcm.org.cn/en-us). Registration on these portals is mandatory for collaborative studies involving those countries. Additionally, such studies must be registered with the CTRI in accordance with ICMR guidelines.

The International Clinical Trials Registry Platform(ICTRP)(https://trialsearch.who.int/), managed by the WHO, is a search portal providing centralized access to a database containing the 20-item trial registration datasets submitted by registries. Partner Registries, such as the Centre for Clinical Trials and Clinical Trials Registry – Chinese University of Hong Kong (http://www.cct.cuhk.edu.hk/cctwebsite/default.aspx), are also available. These registries are affiliated with either Primary Registries in the WHO Registry Network or ICMJE-approved registries.

When submitting a manuscript, include trial registration details, such as the registry name, registration number, and registration date. For example:

"The study was registered in the Clinical Trial Registry-India (registration number: XX, dated XX, YY, ZZ)."

Registering protocols is equally important for systematic reviews, typically in platforms like PROSPERO, an international prospective register of systematic reviews (https://www.crd.york.ac.uk/prospero/). This helps prevent duplication of studies and promotes transparency in the research process. According to the updated 2024 ICMR guidelines (https://ethics.ncdirindia.org/icmr_ethical_guidelines.aspx), systematic reviews that adhere to standard guidelines and procedures, including prospective registration in a recognized registry, do not require submission for EC approval. Alternatives to PROSPERO include Cochrane (https://www.cochrane.org/), Center for Open Science (https://www.cos.io/), and Inplasy (https://inplasy.com/).

Common errors in ethical considerations in manuscripts

1. *Informed consent and assent details not mentioned*

The standard method for obtaining informed consent is written informed consent from adult participants. For research involving children, assent from the children and written informed consent from parents or LAR are required. If alternative forms of consent (e.g., verbal consent) were obtained, this must be

clearly stated along with the reasons for using such methods.

2. Including informed consent in eligibility criteria

As informed consent is addressed separately in the manuscript, it does not need to be repeated under the inclusion or exclusion criteria. Frequently, it is redundantly mentioned under inclusion criteria as 'participants providing written informed consent' and again under exclusion criteria as 'participants not providing written informed consent.' Such repetition can be avoided.

3. IEC approval details not mentioned

A common issue in manuscripts is the lack of complete IEC approval details. The statement often omits the name of the EC, the hospital or college to which the EC is affiliated, the approval number, and the date of approval. Without this information, verifying the status and quality of the EC is difficult.

4. It is 'ethics committee,' not 'ethical committee'

Manuscripts sometimes erroneously refer to an 'ethical committee' or mention 'ethical approval.' This misnomer can imply the existence of 'unethical committee' or 'unethical approvals.' The correct terminology is 'ethics committee' and 'IEC approval.' If using a subheading, 'Ethical Considerations' is appropriate. For example: "Approval was obtained from the Institutional Ethics Committee of XYZ (approval number: XX, dated YY. ZZ)."

5. It is mostly IEC, not IRB

In India, most ECs are referred to as IECs, with some exceptions. The term IRB is more commonly used in other countries.[7] However, IRB is sometimes incorrectly mentioned in place of IEC in the Indian context. It is important to use the correct terminology, referring to the EC as an IEC in India and as an IRB only where applicable. Note that other names, such as ethical review boards (ERBs) and research ethics boards (REBs), are also used in some places.

6. Avoid unnecessary details

Manuscripts sometimes include redundant information, such as adherence to the principles outlined in the Declaration of Helsinki. If IEC approval is stated, it is implicit that the basic ethical principles of research have been followed. Similarly, mentioning IEC approval ensures compliance with the ICMR Ethical Guidelines for Research (2017) principles, eliminating the need for separate mention. As word count is valuable, such redundancies should be avoided.

7. Approval from scientific committees, but not ECs

Many authors from centers without an EC claim that a scientific committee approved their study and that guidelines such as those of the ICMR and the Helsinki Declaration were followed. However, it is insufficient to conduct studies on humans and animals without explicit EC approval, which must be clearly stated in the manuscript. If an institution does not have an EC, approval may be sought from an external EC at a nearby institute or from the IEC(Ind).

8. Waiver from IEC

For certain studies, such as retrospective chart reviews, ECs may grant a waiver. It is insufficient to state in the manuscript that EC approval was not mandatory and, therefore, not sought. Instead, an explicit waiver from the EC must be obtained and clearly mentioned in the manuscript. However, some ECs do not require single case studies or case series waivers. Researchers should adhere to the specific policies of their IEC in such cases.

9. Masking details for anonymized peer review

In journals that conduct anonymized peer reviews, identifying information must be masked during manuscript submission, including details about the EC. It is written in the submitted manuscript as: "Approval was obtained from the Institutional Ethics Committee of (anonymized)." However, these details should be included in the cover letter for the editor's reference. If the manuscript is accepted, the EC details should be re-added in the final version. It is important to note that these policies vary across journals, so it is advisable to verify the requirements before submission.

10. Not mentioning protocol deviations

With research protocols increasingly accessible in registries such as CTRI, editors, reviewers, and readers can easily identify protocol deviations,[8] resulting even in retractions (https://retractionwatch.com/2021/06/01/two-transcendental-meditation-papers-retracted-for-failures-to-report-primary-outcomes/). To maintain transparency, it is prudent to clearly mention any deviations from the protocol in the manuscript, along with the reasons for these changes.

Parting comments

Mentioning EC approval is mandatory for all standard, peer-reviewed journals. Editors are likely to reject manuscripts without this information. Additionally, providing detailed ethical considerations enhances trust in the research among authors, reviewers, and readers.

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Suggested readings

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