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Ethical approval for healthcare research

Ethical approval should be obtained before a research study begins, and come from a recognized ethics committee. Legislation and ethical review board systems vary worldwide for both national and international research. Editors and publishers need assurance that ethical principles have been adhered to when considering research studies for publication. Failure to provide details of ethical approval could lead to a submission being rejected or delayed.

Ethical principles

The principles are based on two key documents (see Further information):

- The Declaration of Helsinki
- The Belmont report (1979)

If ethical approval is not required according to local legislation, authors should state the reason and provide a supporting reference or link.

Research requiring ethical review

The categories include:

- Investigations that involve human subjects
- Clinical trials of medicinal products, medical devices or interventions
- Basic science studies involving procedures
- Studies administering questionnaires or interviews
- Studies with biological samples or data
- Studies with samples or data from a research bank

Journals may request authors to provide ethical review documentation.

Research that may not require ethical review

- Audit
- Service evaluation
- Retrospective or prospective chart review

Note that legislation varies across countries and between individual institutions and organizations.

Ethics statements in submissions to scientific journals

A statement of a work's ethical approval should include:

- The name(s) of the ethics committee(s)
- The reference number(s)
- The date(s) of approval.

Further information

Committee on Publication Ethics Guidance for Editors. Research, audit and service evaluations   https://publicationethics.org/resources/guidelines-new/guidance-editors-research-audit-and-service-evaluations

Health Research Authority   https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/

International Compilation of Human Research Standards   https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

US Department of Health and Human Services. The Belmont report: Ethical principles and guidelines for the protection of human subjects of research   https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

World Medical Association. Declaration of Helsinki – Ethical principles for medical research involving human subjects   https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/