

EDITORIAL**STUDY DESIGN AND ETHICS IN SCIENTIFIC PAPERS**

Good research should be well justified, well planned, and appropriately designed, so that it can properly address the research question. Statistical issues, including power calculations, should be considered early in the study design, to avoid futile studies that produce subject risk without enrollment sufficient to answer the research question. Outcomes should be specified at the start of the study. Research should be conducted to high standards of quality control and data analysis. Data and records must be retained and produced for review upon request. Fabrication, falsification, concealment, deceptive reporting, or misrepresentation of data constitute scientific misconduct.

Documented review and approval from a formally constituted review board (Institutional Review Board or Ethics committee) should be required for all studies involving people, medical records, and human tissues. For those investigators who do not have access to formal ethics review committees, the principles outlined in the Declaration of Helsinki should be followed. If the study is judged exempt from review, a statement from the committee should be required. Informed consent by participants should always be sought. If not possible, an institutional review board must decide if this is ethically acceptable. Journals should have explicit policies as to whether these review board approvals must be documented by the authors, or simply attested to in their cover letter, and how they should be described in the manuscript itself.

Animal experiments should require full compliance with local & national, ethical & regulatory principles, and local licensing arrangements.

Journal recommendations for preferred presentation and analysis of data should be described in the Information for Contributors or Authors. Wherever possible, recommendations should be based on evidence about methods of data presentation that are readable and most likely to be interpreted correctly by readers. Editors should keep themselves informed of this research and adapt their recommendations as it evolves.



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