

Guidance for Editors: Research, Audit and Service Evaluations

Regulations regarding what type of study requires ethical approval vary worldwide. In some countries all studies require ethical approval but in others not. This may lead to submission to journals of manuscripts relating to such studies that do not satisfy the journal's normal requirement for independent ethical approval, and rejection of the manuscript because of misunderstanding of local regulations.

In the UK, for example, the Health Research Authority (HRA), which coordinates and regulates ethical approval of research involving human subjects, specifically excludes projects from requiring ethical approval if they fall into the categories of clinical audit, service evaluation, research and usual practice/surveillance work in public health, even though: (i) they may have considerable ethical implications (e.g. the danger of coercion and threats to autonomy and confidentiality); (ii) their methods may overlap with studies defined as 'research'; and (iii) it may be difficult to decide how to define certain studies, even using the criteria suggested by HRA.

Other countries may have similar restrictions that make it difficult or unnecessary to obtain approval for certain types of study. This guidance has therefore been produced by COPE as an aid to journal editorial teams who are required to review such manuscripts.

COPE recommends that editors reviewing such a manuscript should consider the following, in addition to the usual criteria that are applied during editorial review:

1. Is the study scientifically valid and clearly presented; for example is the sample size adequate, are the results adequately and clearly presented and explained, and have the investigators excluded or considered the possible confounding factors and/or biases? Second, does the study contribute sufficiently to knowledge to make acceptance and publication a possibility?
2. Have the ethical harms been minimised; for example has due care been taken to avoid coercion or exploitation, to protect confidentiality, to minimise the risk of physical and psychological harm and to respect autonomy where possible? (For example, information sheets and consent forms can still be used for certain audits and service evaluations as a demonstration that appropriate ethical standards are being met, even if a research ethics committee has not asked for it). It may be necessary to seek further information from the investigators to establish how they have addressed these issues.
3. Do the benefits outweigh the harms in this particular study's case?
4. If there is doubt about local law or regulations, editors should clarify this with the authors and ask them to provide a letter from the individual research ethics committee or the research ethics authority in that country about the research.

COPE acknowledges that aspects of this process may already be followed by editorial teams as part of their review of papers, and are also similar to those undertaken by research ethics committees themselves when considering applications. It is suggested, however, that following the above scheme may provide a practical framework. Further, it is advised that such deliberations be documented as part of the journal's standard record-keeping. Finally, it is hoped that this guidance will be useful for authors as well as editor.

Reference
Written and approved by
COPE Council June 2008.

Version 1
First published online,
October 2008

Version 2
Revised and published
17 January 2014