Regulatory approval

The reviewer should remember that there is no clinical study without disclosure of ethical protection, committee approval, and the patient's informed consent. Sometimes the journal requires that the clinical study be entered into a registry to be published. The best-known registry is probably www.clinicaltrials.gov, but there are other registries such as www.anzctr.org.au. By registering the study the authors undertake the commitment to avoid the situation in which if the results of a trial are negative, a decision has to be made to either not publish the results or delay publication for an unspecified time [1)].

Conflict of interest, funding information, and other support should be reported, if they exist. The reviewers need to answer the following:

1) if humans are studied, or human tissues or animals are involved, has ethics approval been obtained and is the study ethical

2) is the paper in agreement with the standards of medical ethics

3) is informed consent applied

4) is the study registered

5) are there any conflicts of interest involving the authors?

1)

Chan AW: Out of sight but not out of mind: how to search for unpublished clinical trial evidence. BMJ 344:d8013, 2012