

# Research Ethics Committee. Mandatory necessity. Requirement needed

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The publication of a scientific work is the final stage of any research. A conducted but unpublished research is not disclosed and therefore does not become available to the scientific community or the lay population and it is equal to a search not performed [1], not producing benefits for people. Therefore, the publication is the ultimate goal of the researcher. It has a scientific purpose.

However, until the publication, the researcher should be subservient to strict standards of conduct in order to protect the research subject, the research institution and even the researcher himself. Hence, if the ultimate goal of a researcher is of a scientific character, the path that he must tread must be ethical. The same applies to publishers of scientific journals that aims not only to engage with the scientific quality of their publications, but also to the enhancement of ethical principles.

In the meantime, we evoke the Resolution 196/96 of the National Health Council (CNS) [2], which defines as research involving human beings which, individually or collectively involve humans directly or indirectly, entirely or in parts of it, including the management of information and materials. Importantly, for any type of research to be conducted after the study design, referral should be made to the research protocol to the Research Ethics Committee (REC) of the institution, and only after approval of the protocol is that the study can be conducted. This applies not only to direct research on human beings (albeit involving only questionnaires), but also for experimental research, review of medical records, retrospective analysis, anatomopathological analysis, genetic surveys, social surveys and epidemiological surveys in general.

However, evidence indicates that these requirements are not always followed in publications [3]. Apparently, some researchers have no clear idea of the need for assessment by the REC in the case of research involving humans indirectly (i.e., the reviews of medical records, retrospective analysis) or even directly (case reports or simple application questionnaires) [3]. Likewise, the legal

requirements that ensure the confidentiality of personal data may be missed [3].

Most observational epidemiological studies are based on existing data, usually obtained through retrospective review of medical records. In this case, there is a mistaken consensus that researchers should only ensure the confidentiality of personal data without the need of assessment by the REC [3].

Scientific societies and magazines usually warn the researcher about the need to submit the paper to the REC, but sometimes the monitoring of fulfillment of the requirements is neglected. As exemplified by the cases of abstracts that are presented at scientific meetings in categories known as free topics, in which there is no requirement for proof of appreciation by a REC. The editors and scientific organizations must rectify this problem by requiring adherence to ethical standards of national and international studies that the authors submit for review and publication, whether in regular or scientific events, regardless of type of study carried out [3,4].

Another aspect that must be addressed here is the fact that researchers (and journal editors) are generally more enthusiastic about the publication of studies that show a large effect or a new treatment (positive results) or equivalence of two approaches to treatment studies (noninferiority studies). They are also typically less excited about trials that show that a new treatment is inferior to standard treatment (negative results) and even less interested in trials that are not clearly positive nor clearly negative. This generates a kind of “selective consciousness” in favor of studies with positive results. However, if all intervention studies are registered in a public registry at the beginning of its implementation, several stakeholders in the research can explore the full array of clinical evidence. Then in 2004, the proposal of the International Committee of Medical Journal Editors (International Committee of Medical Journal Editors) appears regarding a mandatory registration of clinical trials

in databases accessible to all, in order to avoid the problem of “ selective consciousness “[5]. One option is already widespread in the *ClinicalTrials.gov* registry, sponsored by the *National Library of Medicine*, USA. Several journals now require this condition for publication of articles from intervention studies.

Addressing directly to medical professionals, it is imperative to quote Article 100 of Chapter XII of the Code of Medical Ethics, for the item Medical Education and Research [6]: “The physician shall not fail to obtain approval of a protocol for conducting research in humans, according to current legislation.” However, current legislation regarding the implementation of research in Brazil is governed by Resolution 196/96 of the CNS and this dictates that for any type of research to be carried out it must be done by forwarding the research protocol to the Research Ethics Committee in the institution, not to do so is not only unethical under the ethical and scientific perspective but also from the ethical and professional standpoint, so that the doctor who does not follow that axiom becomes twofold faulty with the ethical code.

This editorial has the intention and responsibility to clarify on major issues related to ethics in research and scientific publications, informing readers that the editors of the Journal of Cardiovascular Surgery have observed all these rules. In publishing guidelines RBCCV there clear instructions relating to obedience to the ethical conduct of research involving humans (and animals) as well as the approval of projects by the Research Ethics Committees, and they must come, necessarily, accompanied by a Submission Letter, explaining the presence or absence of conflict of interest and lack of related ethical issues [7].

This aspect (the obligation to prove a positive opinion by a REC) is also part of the development of the RBCCV as an emerging scientific journal in the indexing scenario in the *Thomson Scientific* (the main base for indexing in the world), a position which not only the Editorial Board, but also the authors who post here have a duty to ensure, in order to continue to focus (on the scientific aspect, not leaving aside the ethical component) in the international arena.

## REFERENCES

1. Muccioli C. O Comitê de Ética em Pesquisa (CEP) e as publicações científicas. *Arq Bras Oftalmol*. 2004;67:195-6.
  2. Ministério da Saúde. Conselho Nacional de Saúde. Resolução 196/96. Disponível em: [http://conselho.saude.gov.br/resolucoes/reso\\_96.htm](http://conselho.saude.gov.br/resolucoes/reso_96.htm)
  3. Borracci RA, Calderón G, Seoane MR, Perez AC, Doval HC. Revisão ética e termo de consentimento livre e esclarecido nas publicações de pesquisas cardiovasculares na Argentina. *Arq Bras Cardiol*. 2008;90(5):317-21.
  4. Block MI, Khitin LM, Sade RM. Ethical process in human research published in thoracic surgery journals. *Ann Thorac Surg*. 2006;82(1):6-11.
  5. De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, et al; International Committee of Medical Journal Editors. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *N Engl J Med*. 2004;351(12):1250-1.
  6. Conselho Federal de Medicina. Código de Ética Médica. Disponível em: <http://www.portalmédico.org.br/novocodigo/index.asp>
  7. Braile DM. Ao MCT/ CNPq / MEC/ CAPES Programa de Editoração e Publicação de Periódicos Científicos Brasileiros. *Rev Bras Cir Cardiovasc*. 2009;24(4):590-2.
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