

Research involving human beings in instructions to authors in domestic scientific nursing magazines

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Abstract

This study analyzes the rules on ethics in research contained in the guidelines of Brazilian scientific nursing journals. We analyzed 208 journals with the Qualis A1 to C and 52.4% had instructions, but it varied significantly according to the Qualis. Concerning the instructions, 83 reported to ethics committee's protocols, the others mentioned the National Health Council Resolution 196/96, the *Declaration of Helsinki*, national research councils, trial records, the Federal Council of Medicine and commissions of the magazine. The results of this research indicate that it is still high the number of Brazilian scientific journals in nursing which have little concern regarding ethical aspects of research in health included in instructions to authors. Recommendations are quite different even in journals that make references to the ethical aspects.

Key words: Bioethics. Publications. Ethics. Nursing. Research, Ethics.



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Ethical principles that guide research involving human beings have received constant attention in past years, particularly regarding possible abuses by scientific community¹⁻³. However, there are doubts if ethical concern goes beyond scientific publications.

The historical landmark for the first formal rules regarding ethics in research involving human beings was the *Nuremberg Code*, of 1946, through which the scientific community sought to respond to the barbarity of Nazi experimentation within the scope of medical research⁴. Later, in 1964, the World Medical Association (WMA) approved the *Helsinki Declaration*⁵⁻⁷, a set of ethical principles to base clinical research practice and to provide guidance to physicians and participants in experimentation. Such regulation was responsible for arising research protocols involving human beings through analysis by an ethical committee, not related to researcher.



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Brazil materialize its first regulation related to ethics in research involving human being in 1988 with the approval of the National Health Council (CNS) Resolution No. 1/88, a significant progress, but limited, as it reached only researches connect to university hospitals that had ethics committees to regulate their research projects⁸⁻¹⁰. Currently, there are two domestic instrument with legal support dealing with ethical issues in nursing researches: Resolution CNS 196/96, established with the intention of controlling ethical aspects of research undertaken in Brazil¹¹, and the Nursing Ethics Code, published by the Federal Council of Nursing in 1993¹², which regulates the exercise of profession.

Resolution 196/96 targets to safeguard physical, psychological, social, and moral integrity of human beings participating as research voluntaries. It sets out what is research, research protocol, responsible researchers, research institution, promoter, sponsor, risk, harm and research subject, among other definitions. It also describes free and clarified consent, setting out the necessity that the research protocol to present the free and clarified consent term (FCCT), which will be used in investigation. FCCT is the formal document for research subjects, which grants them the right to decide autonomous and voluntarily on their participation in the study¹¹.

In addition to formulate these essential definitions Resolution 196/96 instituted the CEP/Conep System, a set of collegiate with local dimension (ethics in research committee – CEP) national (National Ethics in Research Commission – Conep) that act in articulated manner in evaluating and approving research projects. Thus, in order to be able to undertake a research in Brazil, it is necessary that the study be approved by a CEP¹¹ or by Conep, depending on the type of investigation.

If the excellence of research control system and regulation in Brazil is acknowledged, there are doubts regarding researchers, publication, and scientific dissemination means concern to ethical aspects related to dissemination of studies¹³. Not many publications were found in literature studying the impact and presence of bioethics problematic in current bioethical editorial practice. Consequently, this study aims at analyzing the requirements of Brazilian nursing publications related to ethical aspects of experimentations, seeking to contribute toward continued perfecting of these publications.

Method

The study analyzed the Instructions to Authors section in 208 Brazilian scientific nursing magazines, considering ethical guidance referring to research involving human beings.

In order to select the material, an assessment was carried out in the website of the Coordination for the Improvement of Higher Education Personnel (Capes), in October 25, 2010, to generate a full report on the nursing area. The report indicated 411 magazines of the nursing area – international and domestic.

The access to publications took place through electronic address in October and November 2010. It was opted for selecting only domestic periodicals, as exclusion criteria, achieving 2332 publications in total. It was verified that, when attempting to access them, 24 had their electronic address outdated, and it was not possible to get needed information.

Thus, 208 Brazilian magazines in nursing were analyzed whose electronic addresses were kept updated and access available to users at the time that the study was carried out.

Adopted analytical parameters to visualize and analyze data had the assumptions defined by Amdur and Buddle¹⁴ as basis, as well as by Sardenberg et al¹³, who classify in 10 categories the ethical guidance related to research involving human being:

1. Ethics commission or committee – periodicals that make reference to the necessity of approval and/or analysis of works by ethics commission or committee from the institution where the study was undertaken, independently of other recommendations;
2. Resolution CNS 196/96 – magazines guiding for compliance of norms and guidelines defined in this resolution;
3. Declaration of Helsinki – periodicals in which there is not reference to ethics commission or committee from the institution where the study was undertaken, but quote the *Declaration of Helsinki*, independently of having references to other ethical aspects;
4. Free and clarified consent term - magazines mentioning the request of the free and clarified consent term in research involving human beings;
5. Protocol at Conep – magazines requiring that research to be approved by the CEP/Conep System;

6. Registry of clinical assay – periodicals quoting the importance of registry of clinical assays to undertake research;
7. Guidance to follow ethical principles and norms – magazines that warn authors to follow the ethical principles and norms set by governing legislation;
8. Resolution CFM 1,595/00 – magazines guiding authors regarding approval by the Federal Council of Medicine to undertake research;
9. Internal professional ethics commission – magazines analyzing the study according to professional ethics precepts from the internal commission of referred periodical;
10. Without ethics guidance – periodical that do not come with any reference to ethical aspects related to research involving human beings.

Microsoft Excel 2003 program. .

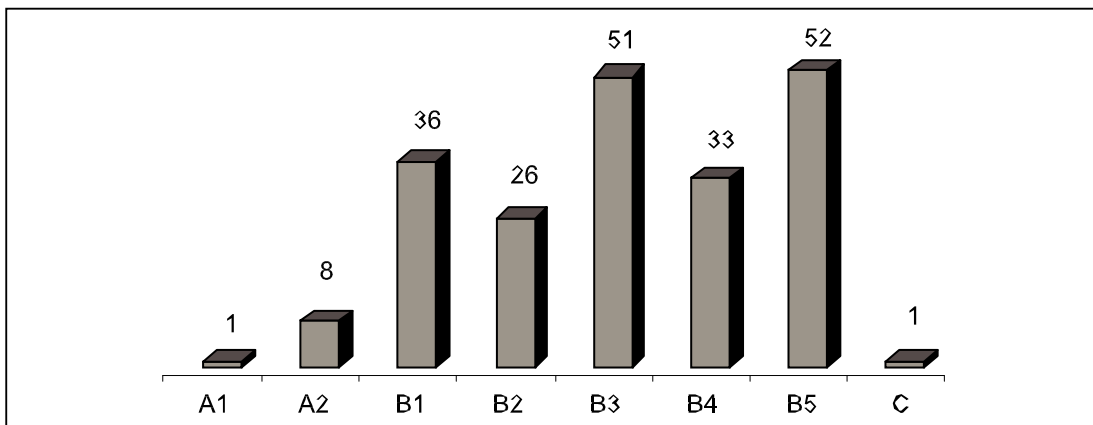
Results

The present study limited itself to analysis of Instruction to Authors, been, therefore, a partial analysis of these periodicals editorial policy regarding ethics. However, one should consider that guidance in the Instructions to Authors section is the sole communication path between the author and the editor, in majority of magazines. One infers from this that the policy adopted by periodicals, reflected in these instructions, covers with great importance in scientific articles publishing practice.

From total of 208 domestic scientific magazines in nursing whose electronic addresses was available, only one Brazilian magazine in nursing classifies as Qualis A1 and eight fit in Qualis B, with emphasis in classification B3 and B5 (Chart 1).

After integral reading of the Instructions to Authors, magazines were grouped according to 2009 Qualis classification, referring to evaluation of Capes periodicals. Obtained data were tabled and submitted to analysis by the

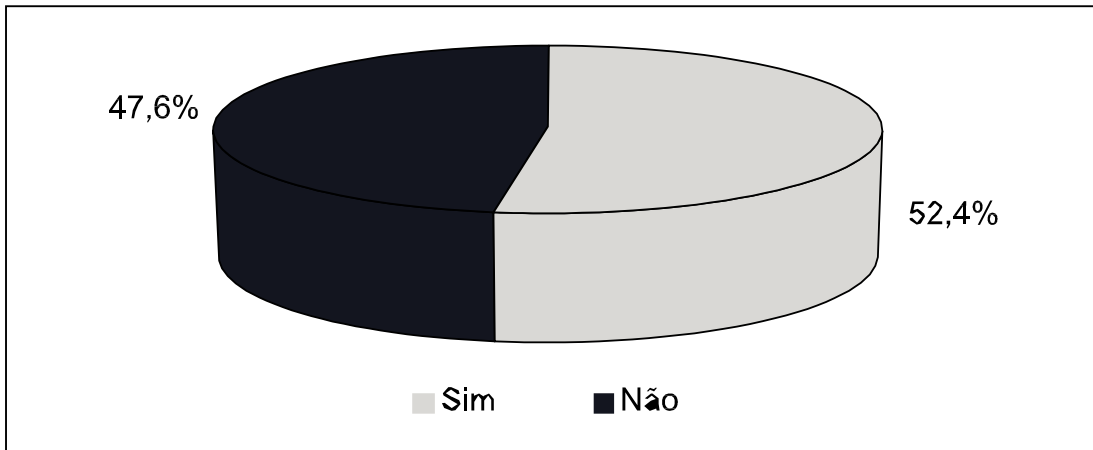
Chart 1 Number of magazines in nursing according to Qualis classification. Ribeirão Preto, 2011



Generally, it was verified in analyzed magazines that 109 (52.4%) come with guidance to authors regarding requirements related to ethics in research (Chart 2). The high percentage of periodicals that do not make reference to ethical precepts that

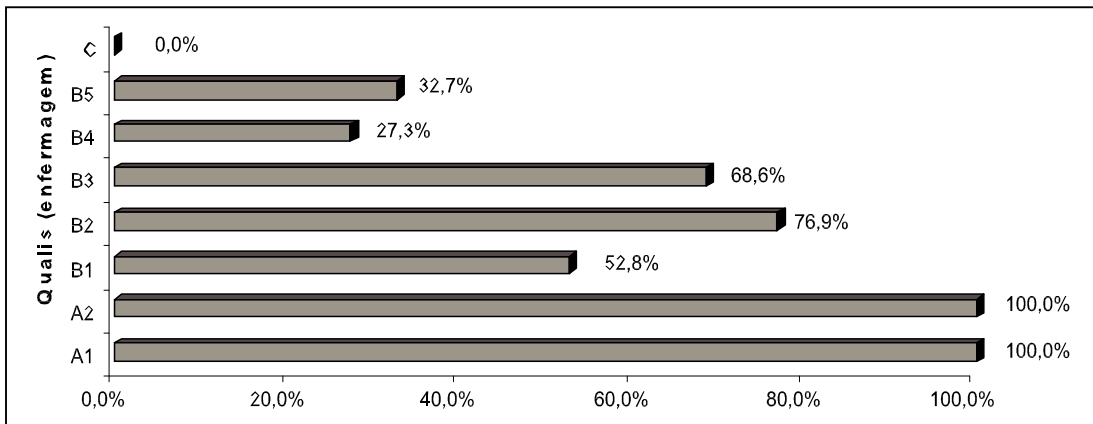
must guide research (47.6%) may be related to these publications in Qualis ranking, that is, they are magazines that do not have high ranking and have lesser requirements for publishing works.

Chart 2 Percentage of magazines in accordance to presence or not of ethical guidance in the instructions to authors section. Ribeirao Preto, 2011



Analyzing the Qualis of the magazines with Qualis B, those of strata B1 have lesser ethical mentions, one verified that all classified number of periodicals that guide authors periodicals with Qualis A, nine make reference to regarding ethical guidance, compared to ethical guidance to authors From periodicals magazines classified as B2 or B3 (Chart classified with 3).

Chart 3 Percentage of magazines that presented ethical guidance in the instructions to authors section, according to Qualis classification. Ribeirao Preto, 2011



These data reveal that the better ranked is the Data pertinent to the kind of guidance offered to magazine greater are the requirement for authors, related to ethical guidance quoted in publishing. However, one considers that the magazines, were analyzed and are synthesized in minimum that any periodical should require is the Table 1. The result shows that 83 magazine require compliance to the ethical norms and guidelines research approval from ethics committees, and 27 regarding undertaking of research involving guide authors regarding compliance to Resolution human beings, in such way that they are not 196/96. It is fit to stress that several magazines complacent with research carry out with doubtful presented more than one request, guidance or ethics means. mention.

Table 1 Number of magazines that presented ethical guidance in instruction to authors section, according to the type of ethics instruction. Ribeirao Preto, 2011

Ethics instruction	Number (*)
	83
Guidance for following Resolution 196/96	27
Declaration of Helsinki	18
Request of free and clarified consent term	9
Request of protocol approval in Conep	6
Registry of clinical assay	5
Guidance to follow ethics principles and norms	5
Resolution CFM 1.595/00	1
Internal Professional ethics commission of the periodical	1
Without ethical guidance	99

(*) There may be more than guidance in the same magazine

Discussion

The increase of research in health areas boosted the development of scientific investigations and clinical assays with human beings¹⁵. Although it is known that any research involving human beings must be adequate to scientific precepts that justify it, in order to respond to uncertainties, prevailing the benefit and assuring subjects of their benefits and rights¹⁶, when analyzing Instructions to Authors of periodicals, it

was realized still a deficit in compliance to such precepts.

The information in Instructions to Authors is the main communication path between researcher and editor, revealing itself as important source of disseminating relevant information from magazines¹³. Studies previously accomplished with similar objectives were carried out in health area and they corroborate with the findings^{13,14,17}, standing out the low mention of the ethical

aspects of research in human beings in make unfeasible publishing research that Instructions to Authors and lack of harm ethics ¹³. systemization regarding requirement.

Final considerations

Although the nursing area is recognized by its concerns regarding ethical guidance ¹³, one considers the percentage of magazines that still do not indicate the necessity for the study to follow ethical precepts as relevant, as well as the approval of research involving human beings by ethics committees. There was little mention related to following the precepts that govern Resolution 196/96 and the *Declaration of Helsinki*, documents related to experimentations in human beings ^{5,11}. Such situation was perceived in publications from different health areas and in several contexts, such as in geriatrics, in periodicals published in the English language, in which only 21% explicitly stated the necessity of previous approval by committees ¹⁸ and in biomedicine, in the English language as well, in which 24% did not make any reference to ethical aspects of research in human beings ¹⁴.

The low number of periodicals that required the free and clarified consent term (9) was surprising also, a document that considers the voluntary decision and commitment in informing risks and benefits for participation of subjects in scientific research, although innumerable projects are remade due to lack of clarity in its writing ¹⁹. Research involving human beings need – without delay – to adequate to scientific principles that pervade ethics ¹⁶ and scientific magazines lack concerning with compliance of domestic and international ethical precepts in order to

Dissemination of knowledge through publication of the outcomes of research undertaken characterizes itself as one of the main evaluation criteria for researchers and graduate programs productivity. Therefore, concern with principles of ethics in outlining and development of study should be priority, since a quality research complies with ethical and legal requirement.

In this sense, the editorial policy of scientific magazines assumes outstanding role in scientific development by establishing requirements related to enforcement of ethical precepts for the development of studies.

In the study, it was verified that the majority of analyzed Brazilian magazines does not mention ethical aspects in instructions to authors. One expects that this reality is altered soon, as by publishing only works from authors that enforce ethical requirements in their research, magazines collaborate in order to studies preserve those that participate of investigation, research subjects, and enforce ethical principles targeted to assure integrity and reliability of scientific production as a whole. In addition to stimulate the quality of scientific investigation, presentation of norms, guidelines, codes, principles and codes of ethics in *Instructions to Authors* contribute, also, for the improvement of quality of the domestic publications themselves.

Resumo

A pesquisa envolvendo seres humanos nas instruções aos autores em revistas científicas nacionais de enfermagem

Este estudo objetivou analisar as normas relativas à ética em pesquisa contidas nas Instruções aos Autores de revistas científicas brasileiras de enfermagem. Foram analisadas 208 revistas com Qualis A1 a C e verificou-se que 52,4% apresentavam instruções que variavam significativamente conforme o Qualis. Quanto às instruções, 83 (39,9%) referiram os protocolos dos comitês de ética, as demais citaram a Resolução CNS 196/96, a *Declaração de Helsinque*, conselhos nacionais de pesquisas, registros de ensaio clínico, o Conselho Federal de Medicina e comissões da própria revista. Os resultados do estudo indicam que ainda é alto o número de revistas científicas brasileiras de enfermagem que não se preocupam com os aspectos éticos da pesquisa e que os requisitos éticos exigidos para submissão dos artigos ainda são muito variáveis.

Palavras-chave: Bioética. Publicações. Ética. Enfermagem. Ética em pesquisa.

Resumen

La investigación involucrando a seres humanos en las instrucciones a los autores en las revistas científicas nacionales de enfermería

Este estudio examina las normas éticas en las directrices de revistas científicas brasileñas de enfermería. Fueron analizadas 208 revistas conforme Qualis A1 hasta C y se verificó que un 52,4% presentaban instrucciones que variaban considerablemente de acuerdo con el Qualis. En lo relativo a las instrucciones, 83 refirieron los protocolos de los comités de ética, las demás citaron la Resolución CNS 196/96 del Consejo Nacional de Salud, la *Declaración de Helsinki*, consejos nacionales de investigación, registros de ensayos clínicos, el Consejo Federal de Medicina y comisiones de la propia revista. Los resultados del estudio indican que todavía es alto el número de revistas científicas brasileñas de enfermería que no se preocupan por los aspectos éticos de la investigación y que los requisitos éticos exigidos para sumisión de los artículos todavía son muy variables.

Palabras-clave: Bioética. Publicación. Ética. Enfermería. Ética de la investigación.

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Authors' participation in article

Authors contributed equally in the authorship of the manuscript, in the stages of data assessment, discussions, data analysis, and in elaboration of the work.