

Guilherme Malafaia<sup>I,II</sup>

Aline Sueli de Lima Rodrigues<sup>III</sup>

André Talvani<sup>III,IV</sup>

# Ethics in the publication of studies on human visceral leishmaniasis in Brazilian periodicals

---

## ABSTRACT

**OBJECTIVE:** To analyze ethical aspects of Brazilian articles on human visceral leishmaniasis, published after Resolution CNS 196/1996, and to analyze the policy on Brazilian periodicals on research ethics.

**METHODS:** An explanatory study with a bibliographical and documental nature was conducted. Selection of publications on research involving human beings since 1996 was performed in the SciELO Brazil database. Gaps associated with editorial policies on medical periodicals, based on information obtained from the “Instructions to authors” section of each periodical, were analyzed.

**RESULTS:** While there were no articles on the compliance with ethical aspects in the first four-year period (from 1997 to 2000), 75% fulfilled at least one of the ethical requirements evaluated in the first year (2009) of a subsequent four-year period (from 2009 to 2012). A total of six out of 11 periodicals indicated that the information about ethical aspects should be mentioned in the body of the article. There were three periodicals that required a letter or document, informing about compliance with these aspects and signed by the author(s), to be sent; two that requested a copy of the document used to obtain the free and informed consent; one that clarified the need of a copy to authorize the approval by the Committee on Ethics in Research; and four in which no requirements of ethical aspects were found.

**CONCLUSIONS:** There was an improvement in the description of compliance with ethical aspects found in articles. Standardization of ethical requirements for human research in Brazilian periodicals is suggested. This could promote compliance with the presuppositions of documents regulating human research.

**DESCRIPTORS:** Ethics, Research. Bioethics. Periodicals as Topic. Leishmaniasis, Visceral. Helsinki Declaration.

---

## INTRODUCTION

In recent years, the theme of “ethics in research on human beings” has been increasingly focused on by part of the academic-scientific community. In Brazil, one of the reasons for this increase is associated with the existence of specific legislation establishing the directives and norms that regulate research on human beings. The Brazilian Health Council Resolution (CNS) 196/1996<sup>5</sup> represents a regulatory landmark for Brazilian scientific research involving experiments on humans. Such resolution was designed with the purpose of protecting participants in studies and guaranteeing the rights and duties of scientists, sponsors, the organizations involved and the government.

<sup>I</sup> Departamento de Ciências Biológicas. Núcleo de Pesquisa em Ciências Ambientais e Biológicas. Instituto Federal de Educação, Ciência e Tecnologia Goiano (IFG). Urutaí, GO, Brasil

<sup>II</sup> Programa de Pós-Graduação em Ciências Biológicas do Núcleo de Pesquisa em Ciências Biológicas. Universidade Federal de Ouro Preto (UFOP) - Campus Morro do Cruzeiro. Ouro Preto, MG, Brasil

<sup>III</sup> Departamento de Gestão Ambiental. Núcleo de Pesquisa em Ciências Ambientais e Biológicas. IFG. Urutaí, GO, Brasil

<sup>IV</sup> Departamento de Ciências Biológicas. Instituto de Ciências Exatas e Biológicas. UFOP. Ouro Preto, MG, Brasil

### Correspondence:

Guilherme Malafaia  
Instituto Federal de Educação, Ciência e Tecnologia Goiano – Campus Urutaí  
Rodovia Geraldo Silva Nascimento, km 2,5  
Zona Rural  
75790-000 Urutaí, GO, Brasil  
E-mail: guilhermebiufop@yahoo.com.br

Received: 2/2/2010  
Approved: 7/28/2010

Despite the growing concern and studies in the area of bioethics,<sup>4</sup> there are still problems and conflicts that need to be overcome. Guilherm & Squinc<sup>9</sup> (2009) emphasize the use of impoverished countries as the locus of performance of studies, production of knowledge and development of products. According to Clotet<sup>3</sup> (2009), the adoption of a common moral standard to resolve controversies about biomedical sciences and high technologies applied to health is also a challenge to modern ethics. Garrafa et al<sup>7</sup> (1999) and Garrafa<sup>8</sup> (2008) emphasize that the democratic use of the benefits resulting from the scientific and technological development is far from being achieved and, consequently, poses a challenge for the 21<sup>st</sup> century. On the other hand, according to what is pointed out by Sanches & Ruthes<sup>16</sup> (2009), new discussions arise as a challenge to bioethics, especially when it comes to biological sciences and the existing triad of religion, science and culture.

However, in addition to these conflicts, there are those associated with ethics in the dissemination of results of research on human beings. When the internationally-imposed concept of “publish or perish” is considered, the scientific community is forced to publish their studies. In this case, ethical questions and the directives on research on human beings stand out as safeguards that need to be taken into consideration, aiming to prevent conflicts in the field of ethics and medicine.

Among the innumerable prevalent diseases that are neglected in Brazil, human visceral leishmaniasis (HVL) was selected as the focus of the present study, because it is a serious chronic disease, potentially fatal to human beings and whose lethality can be as high as 10% if the treatment is not adequately performed.<sup>2,5,11,14</sup> It is estimated that its worldwide incidence is higher than 500,000 new annual cases.<sup>5</sup> Brazil has the highest number of endemic cases of HVL in the Americas (approximately 97% of cases in the continent), recorded in at least 19 states.<sup>a</sup>

Since its discovery in the early 20<sup>th</sup> century, research on HVL has been conducted in animals and human beings to better understand and control this disease. In many countries, the exploitation, coercion and manipulation of the informed consent, on behalf of “the science of their publications”, can still coexist. In this context, the present study aimed to analyze the policy of Brazilian periodicals on research ethics and ethical aspects of articles on HVL, published in the years following Resolution CNS 196/1996.

## METHODS

An explanatory study with a bibliographical and documentary nature was conducted. Articles were selected from the SciELO Brazil database, using the terms

“leishmaniose visceral”, “visceral leishmaniasis” and “*Leishmania chagasi*”, between 1997 and 2009.

Articles involving research conducted out of Brazil, even if they included authors connected to Brazilian universities, and those that mentioned visceral leishmaniasis without the human disease, such as studies on vectors and the biology of etiological agents, were excluded.

The evaluation of ethical aspects included in the body of articles was based on the following questions/instructions: 1) The article deals with the approval of a study by a Research Ethics Committee (REC); 2) It refers to the use of the Informed Consent Form (ICF); 3) It mentions that the study followed the ethical directives established in Resolution CNS 196/1996.; 4) It mentions the date of approval of the study by the REC; 5) It includes the protocol number through which the REC approved the study; 6) It mentions the guarantee of anonymity of participants involved in the research; and 7) It clarifies about the existence of conflicts of interest that could have influenced this study.

The period of time of this study (from 1997 on) is justified by the fact that this is the first year after the publication of Resolution CNS 196/1996. Analyses were made according to four-year periods.

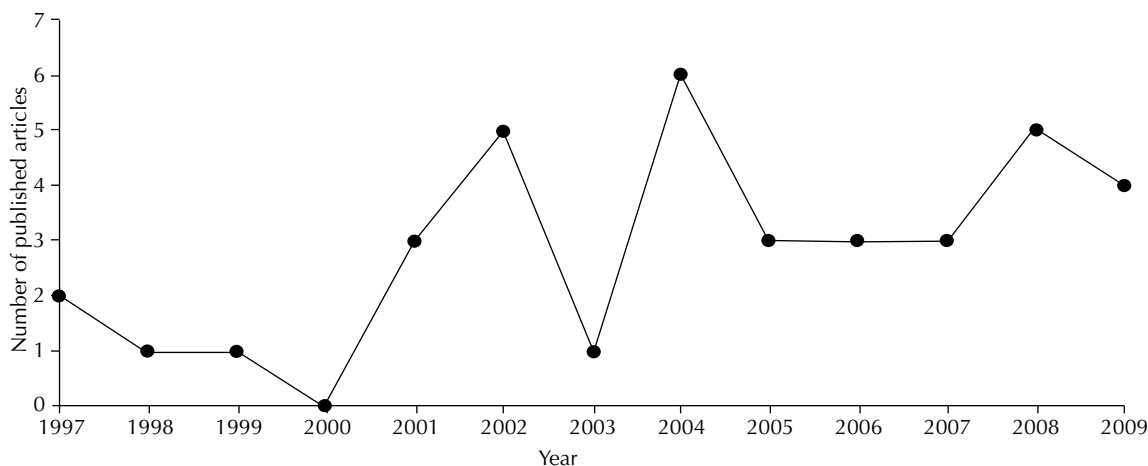
The “Instructions to authors” section, present in the electronic pages of journals, was accessed on January 25<sup>th</sup>, 2010, to evaluate whether scientific periodicals have guided authors to exclusively submit research manuscripts that meet the ethical standards. The following questions/instructions were established according to the content of Resolution CNS 196/1996: to have been the result of research approved by a REC registered with the Brazilian Ministry of Health Research Ethics Committee (CONEP/MS); to have suggested that authors read the documents on ethical questions; to have recommended that authors read extracts or complete documents that regulate research on human beings; to have emphasized the need to use the ICF and to read the ethical instructions of common requirements for manuscripts submitted to biomedical periodicals.

The way editors require veracity of information about the ethical aspects shown by the authors, upon submission of their work, was analyzed according to the instructions described in Table 1. In this group, the questions/instructions sought to evaluate the periodical-authors dynamics associated with the requirement of proofs.

## RESULTS

A total of 76 articles were found for “*leishmaniose visceral*”, 113 for “visceral leishmaniasis”, and 22 for “*Leishmania chagasi*”, totaling 211 articles. When the criteria of exclusion were applied, 37 were selected for

<sup>a</sup> Ministério da Saúde. Secretaria de Vigilância em Saúde. Manual de Vigilância e controle da Leishmaniose visceral. Brasília; 2006.



**Figure.** Number of Brazilian publications on human visceral leishmaniasis indexed to SciELO Brazil, according to year (1997-2009).

analysis. The number of articles annually published was not constant, but rather higher in 2002 (five publications), 2004 (six publications) and 2008 (five publications) (Figure 1).

Table 2 shows the periodicals evaluated and the number of articles published between 1997 and 2009. The *Revista da Sociedade Brasileira de Medicina Tropical* (RSBMT) was responsible for the publication of a third of the articles. The states of Maranhão (Northeastern Brazil), Mato Grosso do Sul (Central Western) and Minas Gerais (Southeastern) were those where the highest number of studies was conducted (seven publications in each).

There was a proportional increase in the number of articles published that mentioned the fact that ethical principles were met throughout the four-year periods analyzed. Whereas the first four-year period (1997 to 2000) included no articles that mentioned this, 75% of articles met at least one of these aspects in 2009 (four-year period from 2009 to 2012).

A total of 22 out of the 37 articles analyzed did not mention that ethical aspects of research on human beings had been met. In addition, eight reported the approval of the study by a REC and two included the date and protocol number of the approval by the REC, as well as the existence or not of conflicts of interest that could interfere with the work developed.

Although the majority (eight out of 11) of periodicals included, in their instructions, the need for approval of the research by the REC of the institution where the study was conducted, none of them emphasized the fact that this REC should have a valid registration with the CONEP/MS. A total of four periodicals recommended that the studies submitted should follow the ethical assumptions included in the declarations, resolutions or

**Table 1.** Guidance on the evaluation of the content of the "Instructions to authors" of the periodicals analyzed.

#### Investigative guidance

Does the periodical clearly indicate that the information about ethical aspects of research on human beings must be mentioned in the text of the article?

Does it require a letter or document signed by author(s) that provides information about the fulfillment of ethical aspects associated with research on human beings?

Does it require a copy of the document that states that consent was obtained from all research participants?

Does it clearly show the requirement that a copy of authorization from the REC that approved this study should be sent?

Is it implicit that the study was conducted according to ethical principles, standards or norms, without the requirement of any supporting document?

Does it contain any information about how authors of manuscripts sent for publication must confirm to editors whether ethical aspects of the study were met?

(national and/or international) ethical codes that regulate research on human beings. No periodicals had the summarized or complete extracts of the documents that regulate research on human beings or information about ethical instructions of the common requirements for manuscripts submitted to biomedical journals.<sup>6</sup> A total of two periodicals included the need for an informed consent form (ICF), completed by the patient participating in the study. In addition, there were no records/instructions on how the ethical aspects of research on human beings should be met in three periodicals.

A total of six out of 11 periodicals clearly indicated that the information about ethical aspects of research on human beings should be mentioned in the body of the article. There were three periodicals that required that a letter or document signed by author(s) be sent, informing

about the fulfillment of ethical aspects of research on human beings; two that required a copy of a document stating that the ICF was obtained from research participants; one that included the need to send a copy of authorization of the study by the REC; and four that did not include any requirements from the editors that ethical aspects of the study should be met.

## DISCUSSION

In developing countries, where the predominance of infectious diseases is high and responsible for the mortality of a substantial part of the population, biomedical studies have received special attention in the sphere of bioethics in the development of research on human beings.<sup>b</sup> Although many results obtained by Brazilian or foreign researchers in national research institutes were published in international journals, there seems to be a growing number who have chosen and valued Brazilian periodicals.

In Brazil, the increase in the number of scientific publications on neglected diseases, such as HVL, is aimed at. This is probably due to the encouragement from research institutions and governmental institutions that promote such research, in addition to the growing quality of Brazilian periodicals. *Cadernos de Saúde Pública*, *Memórias do Instituto Oswaldo Cruz* and *RSBMT* are national periodicals that stand out as means of scientific research dissemination, which are responsible for the higher number of publications on HVL in Brazil, in recent years (Table 2). However, quantity does not always translate as quality. The quality of the scientific production includes aspects such as: 1) the factor of impact of the periodical in which studies are published; 2) measures of centrality of the factor of impact of the area, aiming to make comparisons; and 3) cited half-life of the means of communication. In this case, the number of articles may not guarantee their good technical-scientific quality or unquestioned relevance.

The results show an improvement in the dissemination of ethical aspects of the research on human beings, included in the body of the manuscripts on HVL. This improvement could suggest an advance in the bioethical thinking and approach of researchers, in terms of the fulfillment of ethical assumptions in HVL research, and the importance of editorial directives of medical periodicals continuing to be in accordance with these ethical assumptions, established in Resolution CNS 196/1996.<sup>12</sup>

There was an improvement in the description of the fulfillment of ethical aspects in articles. The initial years when the new legislation was in effect were characterized as a period of transition, a stage of assimilation and

**Table 2.** Number of articles published between 1997 and 2009 per periodical.

Periodicals (ISSN*)	Number of articles published per year
<i>Revista da Sociedade Brasileira de Medicina Tropical</i> (0037-8682) (n = 11)	
1997	1
2001	2
2002	2
2003	1
2004	2
2006	2
2009	1
<i>Memórias do Instituto Oswaldo Cruz</i> (0074-0276) (n = 6)	
1997	1
2002	2
2004	2
2007	1
<i>Cadernos de Saúde Pública</i> (0102-311X) (n = 6)	
1998	1
2002	1
2005	2
2008	1
2009	1
<i>Revista do Instituto de Medicina Tropical de São Paulo</i> (0036-4665) (n = 5)	
2001	1
2002	2
2008	1
2009	1
<i>The Brazilian Journal of Infectious Diseases</i> (1413-8670) (n = 3)	
2002	1
2007	1
2008	1
<i>Brazilian Journal of Medical and Biological Research</i> (0100-879X) (n = 1)	
1999	1
<i>Jornal de Pediatria</i> (0021-7557) (n = 1)	
2004	1
<i>Revista Brasileira de Ginecologia e Obstetrícia</i> (0100-7203) (n = 1)	
2005	1
<i>Revista de Saúde Pública</i> (0034-8910) (n = 1)	
2007	1
<i>Revista Brasileira de Reumatologia</i> (0482-5004) (n = 1)	
2009	1
<i>Revista Brasileira de Hematologia e Hemoterapia</i> (1516-8484) (n = 1)	
2009	1
<b>Total</b>	<b>37</b>

ISSN: International Standard Serial Number, press version

<sup>b</sup> World Health Organization. Ethics and infectious disease. Geneva; 2008[cited 2010 Jan 10]. Available from: <http://www.who.int/bulletin/volumes/86/8/08-056242/en/>

acceptance of new directives. This could be the reason why there were few articles in accordance with the ethical aspects, in the first four-year periods (from 1997 to 2000 and from 2001 to 2004). On the other hand, the joint effort of research institutions to require the approval of studies by the RECs and that made by researchers, who showed higher assimilation and understanding about the importance of meeting ethical aspects, could have resulted in an increase in the number of studies that are in accordance with Resolution CNS 196/1996.

Recent studies indicate flaws in the reporting of information about the fulfillment of ethical questions in the development of research on human beings in the international sphere. Karlawish et al<sup>10</sup> (1999) observed that the majority of publications on elderly individuals living in homes (between 1993 and 1996) do not include the basic norms. Sumathipala et al<sup>19</sup> (2008) showed that one third of the medical publications in Sri Lanka, between 1994 and 2005, informed about the approval of research by a REC. The same was observed by Bavdekar et al<sup>1</sup> (2008) in 7.4% of the medical publications of two major periodicals of India, in 2006, which also reported the use of the ICF. Freeman et al<sup>6</sup> (2008) showed an improvement in the description of ethical aspects in the instructions to authors of medical journals published in English, between 1995 and 2008, although such authors reported the journals' difficulty in checking the veracity of information they were provided. Rowan-Legg et al<sup>15</sup> (2009) pointed out, based on directives given to authors of 103 medical periodicals, the need for greater clarity and standardization of the requirements to meet the ethical aspects associated with research on human beings.

Gaps found in the fulfillment of ethical principles of research on human beings are also present in Brazilian studies.<sup>13,17,18,21</sup>

In the present study, articles on HVL found in Brazil have been conducted according to the ethical norms established by Resolution CNS 196/1996, although it

is not possible to prove the information provided by the text. The number of periodicals that have few or no requirements for studies to be published, in terms of the fulfillment of ethical aspects of research on human beings, is yet relevant.

These data suggest that there are irregularities between the ethical awareness in the institutions that develop research in accordance with the CONEP/MS system and the Brazilian medical periodicals that publish articles on parasitic diseases, especially HVL. Although not being inspection organizations, these periodicals could contribute to the exclusive publication of studies that meet ethical standards. Thus, it is suggested that periodicals should pay attention to aspects such as the instructions on the importance of the REC that approved the study being registered with the CONEP-CEP system, absent in 100% of the periodicals analyzed, and the requirement that a copy of the statement of approval issued by the institution's REC be sent, present in only one article. Rowan-Legg et al<sup>15</sup> (2009) affirmed that adherence to ethical standards in the editorial policies of periodicals that publish research on human beings is important for the scientific community to follow such presuppositions more strictly.

Tavares-Neto & Azevêdo<sup>20</sup> (2009) showed flaws and omissions in the "Instructions to authors" on ethical aspects of Brazilian medical periodicals. By analyzing 20 Brazilian medical periodicals qualified as national level "A" or international level "I" for research on human beings, the authors showed that half of them required research approval from a REC, 35% recommended that such approval be recorded in the body of the manuscript and none required that the RECs be registered with CONEP.

In conclusion, there was an improvement in the description of the fulfillment of ethical aspects in articles. It is suggested that the ethical instructions on research on human beings be standardized in Brazilian periodicals. This could promote the fulfillment of presuppositions of documents that regulate human experimentation.

## REFERENCES

1. Bavdekar SB, Gogtay NJ, Wagh S. Reporting ethical processes in two Indian journals. *Indian J Med Sci.* 2008;62(4):134-40. DOI:10.4103/0019-5359.39551
2. Bern C, Maguire JH, Alvar J. Complexities of Assessing the Disease Burden Attributable to Leishmaniasis. *PLoS Negl Trop Dis.* 2008;2(10):e313. DOI:10.1371/journal.pntd.0000313
3. Clotet J. Por que bioética? *Rev Bioética.* 1993;1(1): 13-9.
4. Cohen C, Vianna JAR, Battistella LR, Massad E. Time variation of some selected topics in bioethical publications. *J Med Ethics.* 2008;34(2):81-4. DOI:10.1136/jme.2006.019091
5. Desjeux P. Disease Watch Focus: Leishmaniasis. *Nat Rev Microbiol.* 2004;2(9):692-3. DOI:10.1038/nrmicro981
6. Freeman SR, Lundahl K, Schilling LM, Jensen JD, Dellavalle RP. Human research review committee requirements in medical journals. *Clin Invest Med.* 2008;31(1):E49-54.
7. Garrafa V, Costa SIF, Oselka G. A bioética do século XXI. *Rev Bioética.* 1999;7(2):207-12.
8. Garrafa V. Novas fronteiras bioéticas: ética no mundo globalizado – uma perspectiva do Brasil. *Rev Port Bioética.* 2008;6:279-90.
9. Guilhem D, Squinca FA. Educação em ética na pesquisa: desafio para a formação de jovens cientistas. *Brasilia Med.* 2009;46(Suppl 1):3-5.
10. Karlawish JH, Hougham GW, Stocking CB, Sachs AG. What is the quality of the reporting of research ethics in publications of nursing home research? *J Am Geriatr Soc.* 1999;47(1):76-81.
11. Malafaia G. Protein-energy malnutrition as a risk factor for visceral leishmaniasis: a review. *Parasite Immunol.* 2009;31(10):587-596. DOI:10.1111/j.1365-3024.2009.01117.x
12. Marques-Filho J. Ética em Pesquisa: Dez Anos da Resolução CNS 196/96. *Rev Bras Reumatol.* 2007;47(1):2-3. DOI:10.1590/S0482-50042007000100002
13. Pellizzon RF, Montero EFS, Población DA, Monteiro E, Castro RCF. Revistas brasileiras publicadoras de artigos científicos em cirurgia. III: análise das instruções aos autores baseada na estrutura dos requisitos de Vancouver. *Acta Cir Bras.* 2007;22(6):511-8. DOI: 10.1590/S0102-86502007000600016
14. Romero GA, Boelaert M. Control of visceral leishmaniasis in latin america-a systematic review. *PLoS Negl Trop Dis.* 2010;4(1):e584. DOI:10.1371/journal.pntd.0000584
15. Rowan-Legg A, Weijer C, Gao J, Fernandez C. A comparison of journal instructions regarding institutional review board approval and conflict-of-interest disclosure between 1995 and 2005. *J Med Ethics.* 2009;35(1):74-8. DOI:10.1136/jme.2008.024299
16. Sanches MA, Ruthes VRM. Ética mundial e cultura da paz: desafios da bioética. *Horizonte.* 2009;7(14):31-45.
17. Sardenberg T, Müller SS, Pereira HR, De Oliveira RA, Hossne WS. Análise dos aspectos éticos da pesquisa em seres humanos contidos nas Instruções aos Autores de 139 revistas científicas brasileiras. *Rev Assoc Med Bras.* 1999;45(4):295-302. DOI:10.1590/S0104-42301999000400003
18. Sardenberg T, Müller SS, Pereira HR, Oliveira RA, Hossne WS. Análise dos aspectos éticos da pesquisa em seres humanos contidos nas instruções aos autores de 38 revistas de ortopedia e traumatologia. *Acta Ortop Bras.* 2002;10(2):15-8. DOI:10.1590/S1413-78522002000200002
19. Sumathipala A, Siribaddana S, Hewege S, Lekamwattage M, Athukorale M, Siriwardhana C. Ethics Review Committee approval and informed consent: an analysis of biomedical publications originating from Sri Lanka. *BMC Medical Ethics.* 2008;9(1):3. DOI:10.1186/1472-6939-9-3
20. Tavares-Neto J, Azevêdo ES. Destaques éticos nos periódicos nacionais das áreas médicas. *Rev Assoc Med Bras.* 2009; 55(4):400-4. DOI:10.1590/S0104-42302009000400013
21. Tenório MCM, Bezerra J, Tassitano RM, Barros MVG, Costa AM. Ética na pesquisa com seres humanos: revisão dos artigos publicados na Revista Paulista de Educação Física (1996-2004). *Rev Bras Educ Fis Esp.* 2005;19(4):329-35.

---

The authors declare that there are no conflicts of interest.