

# EDITORIAL ESPECIAL SPECIAL EDITORIAL

## As modificações propostas para o parágrafo 30 da Declaração de Helsinque 2000 diminuirão os requisitos relacionados ao acesso aos cuidados de saúde para os voluntários de ensaios clínicos

*The proposed changes for Paragraph 30 of the Declaration of Helsinki 2000 will reduce requirements relative to healthcare access for clinical trial volunteers*

### Dirceu B. Greco

Professor Titular,  
Departamento de  
Clínica Médica,  
Faculdade de Medicina  
Coordenador do  
Serviço de Doenças  
Infecciosas e  
Parasitárias,  
Presidente do Comitê  
de Ética em Pesquisas  
Universidade Federal  
de Minas Gerais, Belo  
Horizonte  
greco@medicina.ufmg.br

## Introduction

*The discussion on the ethical requirements for conducting biomedical research in developing countries has gained considerable visibility in the past few years<sup>(1,2,3,4)</sup>. Such interest has been fueled by the pressing need for research related to the AIDS pandemic, by the resulting increase in research in developing countries and by the fact that 90% of global research expenditures are for diseases that affect only 10% of the global population<sup>(5)</sup>. Although some diseases being researched are present worldwide (hence the inclusion of volunteers from developing countries), it is extremely worrying that so little is invested in the study of many diseases that affect billions of people, chiefly in poor countries. Moreover, in spite of the progress of science and technology, their benefits rarely reach developing countries. Billions of people still live with intolerable levels of poverty, with scarce access to healthcare and lacking the most basic medications<sup>(6)</sup>. In this manner, for scientific progress to accompany moral progress, standard of care must improve gradually and investments should be directed, preferably, to the development of studies that are relevant to health policies and increase the local capacity of health providers in relation to science, ethics, and medical care.*

*This introduction emphasizes the importance of implementing internationally accepted ethical guidelines that contribute to the improvement of health services for all those who need them, one of the greater problems of our time.*

## Ethics in international research and global health

*It is worth emphasizing that, undoubtedly, effective vaccines and more potent medications are urgently needed to halt the spread of many diseases, including HIV/AIDS, and research with human beings will be needed. This can be confirmed by the estimated 16,000 new daily cases of HIV*

infection (UNAIDS)<sup>(7)</sup> with over 90% of these cases occurring in the third world. The same situation can be seen with other diseases like tuberculosis, leishmaniasis, malaria, Hansen's disease and hepatitis. What is unacceptable is that this urgency be used as a justification to reduce the ethical standards established for clinical trials<sup>(8,9,10,11)</sup>. Particularly, there have been attempts to undermine the Declaration of Helsinki<sup>(12)</sup>, the paradigm for research ethics for a long time.

We must remember here that although the Declaration of Helsinki is a document of the World Medical Association, the values it establishes and the principles it expresses do not "belong" to the WMA but are the values of the world community, including the poor and marginalized majority.

**Background:** With the sophistic argument that poor countries do not have equal access to ideal treatments (the most common example is related to the access to medication for the treatment of AIDS), there has been, in the past five years, a combined and continuing action to reduce the ethical requirements defended in the Declaration of Helsinki<sup>(13,14)</sup>. The most controversial items are those related to healthcare access and to the use of placebos as an experimental control.

### **The proposed changes for the Declaration of Helsinki**

The latest significant amendment to the Declaration of Helsinki was adopted at the general assembly of the World Medical Association (WMA) in 2000 (Edinburgh), where, in spite of intense North American pressure to the contrary, the restrictions on the use of placebos prevailed (item 29 – placebo can only be used for a control group when there is no effective treatment), while Paragraph 30 (access of volunteers to healthcare) was thus worded: "At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study". In this manner, it included the obligation of

*providing volunteers with the best healthcare after completion of the trial. Thus, it maintained the prohibition of a double standard for treatment, that is, volunteers shall be treated equally, regardless of their place of origin or income level. However, this partial victory has been constantly threatened by the continuous pressure for lesser strict ethical requirements for developing countries, made by regulating agencies, sponsors and researchers, notably from the United States.*

*In 2002, the WMA published a Note of Clarification for Paragraph 29, adding exceptional situations for the use of placebo, even when there are effective treatments available. This would be the first step and risk to facilitate research in developing countries that the researchers would not be allowed to conduct in their countries of origin.*

*For the 2003 General Assembly (Helsinki, September 10 to 14), the WMA made available, on its webpage ([www.wma.net](http://www.wma.net)), on August 13th, 2003, an Amendment Proposal and Note of Clarification on Paragraph 30 (access of volunteers to healthcare), giving the extremely short time of 17 days for comments. This Note and Amendment, if approved, would facilitate the establishment of a double standard of treatment, that is, where there is poor access to healthcare, researchers/sponsors would be exempt from the responsibility of providing the necessary treatment for research volunteers, so long as they explain that possibility a priori to volunteers. This change would facilitate transferring projects currently regarded as unethical in industrialized countries to peripheral countries. Moreover, it would practically annul paragraph 19, which contains the fundamental requirements for research (Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research).*

*It is worth stressing that today the discussion on access to healthcare has already gone beyond the controlled terrain*

of research projects and has reached real situations of access to all. Examples include the Global Fund for HIV, Tuberculosis and Malaria and the WHO/UNAIDS Program for global access to anti-retroviral treatment for AIDS patients, where the question is not whether everyone should be provided access to treatment, but rather how and when to implement it. Another example is the decision of multinational corporations (Heineken and Daimler-Chrysler in Africa) that already provide free access to anti-HIV treatment for their employees and their families<sup>(15)</sup>.

**The Brazilian Proposal:** with this untimely and undesirable amendment proposal for the Declaration of Helsinki, the Brazilian Society of Bioethics, the Brazilian Medical Association, the Brazilian Medical Council, the National Commission on Research Ethics, and the Ministry of Health (represented by the Department of Science and Technology and by the National Coordination on STD/AIDS) met in Brasília on August 19, 2003, to discuss this issue. This meeting gave rise to the following proposal against the changes suggested by the WMA: postpone any possible changes to the Declaration of Helsinki, providing a longer discussion period, and involving more people and entities; the suggestion was also made to cancel the Note of Clarification, and even to disregard the notes, which could gradually weaken the document.

The Brazilian proposal was forwarded electronically and defended in the plenary session of the Assembly of the World Medical Association in Helsinki. With the presence of more than 50 representatives of Medical Associations from many countries in the world, the proposal was presented on September 10, along with the opinions received electronically during the 17 days it was posted on WMA's webpage.

With the participation of several countries, some clearly favorable to the proposed changes, the resolute and well founded position against the proposal to change Paragraph 30 (submitted by the workgroup), and favorable to a broader discussion of the

issue, clearly promoted by Brazil, Argentina and South Africa was put to a vote and won.

Thus, the General Assembly established another Workgroup to consider the conflicting points and prepare the report to be presented in the meeting of WMA Board (May 2004), for future decision at the 2004 Assembly (which will be held in Japan). Representatives from South Africa, Germany, Brazil, the United States, and the United Kingdom make up this workgroup ([www.wma.net](http://www.wma.net)).

**Conclusion:** phase III trials (efficacy) with new medications or vaccines are necessary and should be carried out where access to the best proven diagnostic and therapeutic methods are provided. This decision will be safer and ethically correct. If upon completion of the trial, the product is shown to be effective, there must be international pressure to make it available (and affordable) for use in other countries. The urgency, therefore, is not only to research better preventive methods, and more effective medications and vaccines, but also for them to be available to those who need them. Furthermore, if there were no economic limitations, the availability of the best diagnostic and therapeutic methods would be the global standard. The pressure for changes both in CIOMS Guidelines and in the Declaration of Helsinki is economic and is neither ethically nor scientifically founded.

As to the use of placebos, although the text of the Declaration of Helsinki of 1996 prevailed, the pressure primarily from the pharmaceutical industry and US regulating agencies played a significant role in the recent "flexibilization" adopted by WMA (2002), facilitating the use of placebos even when effective intervention exists. There is a real risk that this "flexibilization" may be extended and misused, especially in vulnerable countries/populations. The cooperation of scientists, activists and all society is essential to avoid the reduction of the ethical requirements currently defined in the Declaration of Helsinki.

In short, there will not be egalitarian

*participation in research nor fair distribution of its benefits, unless there is universal access to good quality healthcare, fair and internationally respected ethical standards, and education and social control. In order to reverse the current situation, intense changes in the world order will be necessary to reach the expected equity and the fair distribution of resources, which will certainly decrease the vulnerability of all those involved.*

*Unfortunately, the health disparities will not be solved only through standards and guidelines that regulate research and researchers, but also by people being treated as equals in studies involving human beings; thus, justice will be possible and it may serve as a spearhead for the greater objective of equity.*

*In this manner, making sure that equity will be respected in clinical research can be a meaningful step towards reversing the current injustice in the allocation of resources for health care and can contribute to empower people (volunteers, researchers and society), making them aware of their rights as citizens and fight for them. If this equality cannot be reached even in the well-controlled environment of clinical trials, how can we make it happen in the real world?*

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