


**Post-Graduate Program and Unesco`s Cathedra of Bioethics**
**University of Brasília, Brazil**

# DECLARATION OF HELSINKI 2008 –

# A LATIN-AMERICAN CRITICAL VIEW

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# INTRODUCTION

**CLINICAL RESEARCH** – **Amateur activity** in the eighteenth century; **university activity** in the nineteenth century and, finally, an **industrial activity** in the twentieth century.

**TODAY** – Private funding clearly holds supremacy over investments.

**RECENT YEARS -** International multicentre randomised clinical trials have become the model par excellence for research on new medications.

**BRAZIL 2008 –** 250.000 people participated as subject in research of this tipe.


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## CLINICAL RESEARCH AND GLOBALIZATION

- The power of the market in the field of medications and clinical research is a fact of life.

- There are around 80,000 pharmaceutical industry representatives in the USA, 17,000 laboratory representatives for 130,000 physicians in Germany, thus giving a ratio of 7.64 physicians for every sales representative, similar to what is found in Great Britain, France and USA.

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A country's **"research capacity in the biomedical field"** is taken to mean the set of the following requisites: a) its capacity to define research priorities according to the main health problems of its population; b) its financial independence for investing in priority research; c) its ability to assess and supervise the ethical regulations for research conducted within its own territory.

The internationalisation of research may be beneficial for poor and developing countries if sustainable programs for developing the investigative capacity of the countries hosting such research projects can be added to the profit requirements of the funding institutions.




This is possible through bilateral agreements between the funding institutions and the host countries, bearing in mind two objectives: a) that the research should seek therapeutic, preventive or diagnostic methods relating to the resolution of health problems that are a priority for the populations of the participating countries; b) that accomplishing the research should enable technology transfer and development of skills of advanced investigative practices that can contribute towards achieving independence for the country regarding knowledge production. Under such conditions, the research can certainly be called **cooperative**.

This line of reasoning becomes indispensable to the present discussion, for two reasons:

a) problems reported over recent years regarding clinical trials developed in peripheral countries that may have harmed the subjects involved in them;

b) the attempts, now successful through the modified Declaration of Helsinki 2008, to change the Declaration regarding its old items 19, 29 and 30, which relate to the use of placebos and the care required in this and to sponsors' responsibility towards subjects once the study has been concluded.

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# THE CONCEPT OF SOCIAL VULNERABILITY

There is a consensus regarding the factors determining the **social vulnerability**: lack of resources like income, information, knowledge and technology; lack of access to the public authorities and other types of social representation; limited network of social relationships; diversity of beliefs and customs among the majority of the population; advanced age; and physical deficiencies.

This definition leads to contexts of fragility, lack of protection, debility, disadvantaged states (disadvantaged populations) and even to neglect or abandonment, encompassing various forms of social exclusion or isolation of certain population groups from the advances, discoveries or benefits that may already be underway within the dynamic process of world development

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# DOUBLE ETHICAL STANDARD IN CLINICAL RESEARCH

The expression “double standards”, in relation to clinical research, arose within the international scientific context from two papers published in the late 1990s that made reference to studies that had earlier been sponsored by the NIH / USA.

1997 – Clinical trials in 15 countries to study prevention of vertical transmission of HIV/AIDS from pregnant mothers to their babies ;

1999-2000 - project developed in rural areas of Uganda with the aim of delineating the risk factors associated with heterosexual transmission of HIV type 1 = risk of infection by the virus and the relationship between viral load and heterosexual transmission.

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## BRIEF HISTORY OF RECENT MODIFICATIONS OF DH

The international debates which emerged due to the two aforementioned researches, and it's relation to the double standard pattern used in the care that was given to clinical studies human subjects, led to several discussions in the WMA - organism responsible for the DH and it's periodically actualizations.

* 1997 – Tel Aviv = initial proposal of changes;
* 2000 – Edinburgh = small changes;
* 2003 – Helsinki = proposal for amendments;
* 2004 – Tokyo = no changes; only a "clarifying" note – USA out…;

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## THE 59th. WORLD MEDICAL ASSEMBLY, SEOUL, 2008

In October 2008, at the 59th Annual Assembly of the WMA in Seoul, Chorea, and after several prior preparatory meetings, the changes debated here were ratified [18]. In addition to substantive changes in the items in dispute, the intention of changing the structure of the document, as already advocated by some directors of the WMA since Edinburgh 2000, was implemented. Thus, the well-known paragraphs 19, 29 and 30 changed their numbering within the context of the document, thus losing a little of their "visibility". The significant identifiable changes were the following:

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Paragraph 14 – Protocol with arrangements post-study...

Paragraph 32 – Second part: justification to the use of placebo...

Paragraph 33 – At the conclusion of study... access to intervention identified as beneficial in the study or to other appropriate care of benefits.

Paragraph 35 – if in the physician`s judgement… where appropriate…


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Because of the historical strength that the Declaration of Helsinki has achieved, it has ended up becoming a worldwide technical document that is taken as a moral reference and often placed above countries' own legislation, based on its unanimous worldwide acceptance. What is feared with the decision in Seoul in 2008 is that, because of all the historical divergences recounted, it may become contested and thus lose the moral authority achieved over all these 40 years in which it has been the reference point in clinical research, for researchers, universities, laboratories, companies, scientific journals and even countries, all around the world.

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BRAZIL: Contested the position adopted by the WMA against the use of placebo in research involving human beings, in cases in which there is a proven preventive, diagnostic or therapeutic method for the problem in question and "…the benefits, risks, difficulties and effectiveness of a new method should be tested by comparing them with the best present methods" .

It is very likely that countries such as South Africa, Portugal and Uruguay, which also voted against the new text, will also soon express their views on this matter, as will other nations in the southern hemisphere that are known to have similar positions.

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CORDOBA / Argentina - 14 November 2008 - Congress of the Latin-American and Caribbean Bioethics Network of UNESCO (Redbioética), where have participated 300 researches from 12 Latin-American countries. In the event's final plenary it has been approved, by general agreement, the *Declaration of Cordoba about Ethics in Researches with Human Beings*, which proposed to the countries, governments and organisms that dedicate their work to bioethics issues, to refuse the 6th version of the Declaration of Helsinki, which has been approved in Seoul, South Korea. It recommends as an ethical and normative frame of reference for this issue the principles of the *Universal Declaration on Bioethics and Human Rights* , proclaimed by acclamation in October 2005 in the UNESCO General Conference.


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The Declaration of Cordoba still alerts that: ”The new version of the DH can seriously affect the safety, the well-being and the rights of persons who participate as volunteers in medical studies protocols; the acceptation of different patterns of medical care - which may happen due to methodological, scientific or other reasons - as well as the new possibilities for using placebo, are considered ethically inacceptable practices and are contrary to the idea of human's dignity and human and social rights; and, additionally, the lack of hard post-study obligations in relation to the persons who volunteered participate of the studies and to the host communities, offends people's integrity, amplifies the social inequity and injures it's own notion of justice”.


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## FINAL CONSIDERATIONS REGARDING PERIPHERAL COUNTRIES` OWN REGULATION AND SOCIAL CONTROL SYSTEMS

International research should continue to be carried out. It is also indispensable that the documents and mechanisms created internationally to control and develop such research should be produced and implemented. However, for the process to be as transparent and fair as possible, and to dismiss any doubt regarding undesirable external interference or influences that disregard the social vulnerabilities that exist, the most appropriate way forward is for poor and developing countries to create their own autonomous regulatory systems, with transparent social control mechanisms that are operated democratically at all levels.


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International standards and guidelines are indispensable for providing the direction to be followed in developing clinical research in each place around the world. However, the peculiarities of each country's regulatory systems should definitively be constructed in accordance with each country's particular characteristics and needs. Autonomy is related to the independence to decide and is also related to the technical and intellectual capacity that peripheral nations must cooperatively put in place, in order to achieve this level of autonomy and development, with support from the more advanced nations and from international organisations, for constructing ethical control rules and systems for their biomedical investigations. as

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