

## Research ethics – Global topics

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A recent controversy in the British Medical Journal discusses whether or not the Declaration of Helsinki is dead (Schüklenk 2007). The document was proposed by the World Medical Association in 1964 as a response to the atrocities committed by medical doctors during the Nazi regime. They were war crimes performed in vulnerable populations in name of the scientific progress. In over forty years, the Declaration of Helsinki has become a reference text for the most important international documents regulating research ethics. It is a document that guides medical research but also an ethical register of which principles and protections should be guaranteed in any study on human beings.

The debate about the contemporaneousness of the Declaration of Helsinki was initiated by a letter that announced “The Declaration of Helsinki is dead”, a critical allusion to its capacity for orienting international

research on human beings (Noble 2007). A flood of letters arrived at the journal, an indicative of the importance of the document to the debate on research ethics. Some of the points suggested by the letters are now faced by this Research Ethics Supplement: from the pertinence of the document to guide all research, the challenges of the informed consent among vulnerable populations to the new issue of the benefit sharing after finishing a research. In fact no other piece of ethical regulation has been so intensely discussed as the declaration.

Other ethical texts have been proposed, such as the Belmont Report and the Guidelines of the Council for International Organizations of Medical Sciences (CIOMS), but even today the Declaration of Helsinki receives international attention when a new revision process is announced (United States of America 1979, CIOMS 2002). The most recent revision occurred at the

World Medical Association meeting in October 2008. The main change was that of Article 30, now Article 33, which deals with the participants' benefits after a study has been finished (World Medical Association 2008). The article is known as that of "benefit sharing". The new text clearly demands that the research protocols explicit how the participants will have access to the study's benefits; moreover, access to the benefits must be informed and guaranteed before beginning the research. For the regulation of international multicentric research, especially that sponsored by developed countries but conducted in developing countries, this change will provoke a turnaround in current practices.

This new article of the Declaration of Helsinki, which is substantial in the ethical precepts that regulate international research, responds to the demands of many developing countries. Its due application will demand that the ethical review systems in each country determine how this guarantee will be offered, how long the participants will have access to the benefits, who will be responsible for offering them, and who will be defined as the beneficiaries after the completion of the investigation. As the new version of the document mentions *studies*, not only clinical trials, as it used to, there is also the possibility that other research designs could be considered in light of this array of shared benefits. The idea that the feedback of the results to the participants could be characterized as a way of sharing post-study benefits will be a central category for the ethical review of social research projects employing qualitative investigation techniques.

Qualitative research techniques launch a series of challenges for the current Brazilian ethical review system. Initially conceived to guide clinical trials on human beings, the regulation systems are little sensitive to the characteristics of social research, especially studies that utilize qualitative fieldwork techniques or qualitative procedures for data analysis. Social research became part of the committees' routine work as a result of the demands created by academic journals and funding agencies. The general rule is that all research projects with human participants should be reviewed by ethics committees before the data collection but social researchers did not participate in the committees' genesis or initial composition. Social researchers' pressure over the last few years for more inclusive systems has exacerbated the gap between the practice of social research and the committees' working rules.

This understanding that all fields should be submitted to the committees' ethical review is challenging. On the one hand, the review procedures do not reflect the particularities of social research based on the encounter between the researcher and participant, where subjectivity and reciprocity are central values in the methodological design. On the other hand, there are few committees with members trained social research designs, in spite of the fact that there is a hegemony from the biomedical perspective to research. The result has been an intense criticism of the ethical review systems from the social

scientists. It has initiated a revision of the committees' work practices, such as expedited review for minimum risk studies and the possibility of oral informed consent. Both procedures are more sensitive to social science perspectives.

A new chapter in the Brazilian debate will be initiated with the most recent version of the Declaration of Helsinki. It demonstrates how the document is not dead. In Brazil, the National Research Ethics Commission (Conep) is a regulatory and normative ethics review agency. Created in 1996 by the National Health Council, the CEP/Conep system is composed by 586 committees, and it is a reference for Latin America for its regulatory structure and its presence in universities, research centers, and hospitals. In the last ten years, Brazil has assumed an international position in leading the successive revisions of the Declaration of Helsinki. Some key discussions, like benefit sharing, has been one of the issues on the Brazilian agenda since the 1990s (Greco 2004, Lurie & Greco 2005).

This Supplement on Research Ethics announces some of the topics that have accompanied the history of research ethics since the proposition of the Declaration of Helsinki up to its most recent revision—the history of Nazism, the Nuremberg Code, the Tuskegee experiment, the Belmont Report, and the CIOMS Guidelines. The papers also deal with some contemporary questions whose argumentative challenge is unsettling for the research ethics committees' work. From recurrent topics in the international debate, such as the meaning of the informed consent form or the access to post-study benefits, to questions that have been scarcely discussed by the Latin American bioethics, such as payment for participation in studies or the social research methodologies. These are some of the questions faced by a group of authors who represent the disciplinary and argumentative diversity of the international community in research ethics.

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Anthropologist and tenure professor at the University of Brasilia. Nowadays she is a senior researcher at Anis: Institute of Bioethics, Human Rights and Gender, an independent group which she co-founded, and researcher at the National Council of Research (CNPq). She has 63 peer review papers, 47 book chapters, 7 books, 9 edited books, 98 newspaper articles, 5 films and 43 awards. She develops research about bioethics, research ethics, reproductive rights, secular state and disability, sponsored by CNPq, Ford Foundation, Prosare, Finep and Ministry of Health. She is co-editor of *Developing World Bioethics* journal and co-editor of original paper of RECIIS, and also a member of the editorial board of 9 peer review journals. She is the head of the research ethics on social science committee at the University of Brasilia. Her most recent edited book, "By the cinema lens: bioethics and research ethics", in partnership with Dirce Guilhem and Fabio Zicker, was nominated for the Jabuti Award as the one of the top ten best books in 2008.

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Andréa Sugai is a PhD candidate of Social Policy and Public Health at the University of Brasilia, which topic is the systems of research ethics review: a comparative analysis between the Brazilian and Canadian systems. She is a MSc in Clinical Nutrition/Epidemiology by the Federal University of Bahia (2001), Especialization in Functional Nutrition (2008) and Graduate in Nutrition by the University of Brasilia (1991). She serves currently as a researcher in bioethics and research ethics at the Institute of Bioethics, Human Rights and Gender (Anis) and PAHO (Pan American Health Organization), a pedagogical advisor in a Distance Learning Course in Ethics Research (sponsored by University of Brasilia, Health Ministry and Science and Technology Ministry), member of the Research Ethics Committee of the Humanities Institute, University of Brasilia, and is advisor in nutrition in the Island Children Project (Alagoas, Brazil), coordinated by Anis. Still by Anis, she has developed projects on Bioethics and Ethics Research supported by PAHO and Health Ministry. She is co-organizer of the second edition of the book, *Ethics Research: Training experience in South-African Countries* (Letras Livres and EdUnB, Brasília, 2008), with Debora Diniz, Dirce Guilhem and Udo Schüklenk.