

A critique of Brazil's current research ethics committees

Petrópolis, October 29, 2013.

Dear editors,

In recent decades, the historiography of health in Latin America has found a vital vehicle in *História, Ciências, Saúde – Manguinhos*. More recently, it has also occupied the virtual space of this outstanding journal. With this in mind, I feel that the editors took an auspicious initiative when they opened the blog to the discussion of Brazil's research ethics committees.

While we have stood by somewhat hesitantly and non-assertively up to this point in Brazil, we have witnessed a growing flood of bureaucratic infringements on researcher autonomy, like demands for mountains of research reports and pressure to boost our production in quantity, not necessarily in quality. The model from the biomedical sciences has brought "unexpected effects," such as the epidemic of multiple authorship, which appears to be identical to what has traditionally been seen in the experimental areas of medicine – even the brevity of the articles. Not to blame anyone, but it is time for caution.

A recent example, and undoubtedly one of the most worrisome, comes in the form of the ethics committees tied at different levels to the Brazil's National Committee for Ethics in Research (Comissão Nacional de Ética em Pesquisa, Conep), whose members are appointed by the Health Ministry's National Health Council (Conselho Nacional de Saúde, CNS). The Council is legally responsible for establishing ethical guidelines for health research; sadly enough, the enacted guidelines extrapolated the terrain of clinical trials and experiments. Conep itself has apparently misinterpreted CNS's role, understanding it to have a mandate to impose excessive standards and requirements that restrict scientific research activities in general, even in the social sciences and humanities.

Research in the sphere of health – including studies within the social and human sciences (the anthropology of health, the history of health, research in personal and public archives, and so on) – is now subject to a convoluted and unacceptable process of evaluation by the Research Ethics Committees (RECs) attached to Conep. Their standards classify the research conducted in our areas according to the same strict tenets applicable to the biomedical sciences, as if our research consisted of clinical trials, genetic research, the use of placebos, or laboratory experiments on human subjects.¹ In 2011, CNS created the Plataforma Brasil (Brazil Platform), a database that requires the registration of research "involving human

¹ See the pathbreaking book edited by Paul A. Freund, *Experimentation with Human Subjects*, New York, George Braziller, 1970, which clearly set the distinct ethical boundaries applicable to medical research, sociological, and anthropological field practices.

subjects” – an attribution of practically universal characteristics, making this database a kind of Minotaur of Brazilian science.

Some topics in social research in health warrant comment. Studies of blood donors or blood recipients, or of blood transfusion and blood products, must be conducted in strict compliance with ethical standards. Yet such standards will differ depending on whether, for instance, the research: (a) addresses public policy in the sector; (b) offers an ethnography of gift exchange; or (c) involves the use of blood products and the protection of human health. Strictly speaking, the third type of research project will have to be submitted to an REC under the aegis of Conep and the Brazil Platform database. The first two projects, however, should not be subject to these standards but rather to human and social science committees – without disregarding the requirements of an ethical nature. The cited examples regarding public policy and blood products show how one same topic can generate a complex gamut of research projects, and this means that such projects must undergo a distinct kind of evaluation in the realm of ethics.

Let us take two other examples: (a) a study on social representation among patients in long-term care beds or facilities, and (b) a research project on the work of sanitarians in public health reform. In both cases, researchers must submit their projects to one of the Conep ethics committees. (Strictly speaking, they will have to subject “themselves,” as one’s very academic life has come to depend upon how one’s projects are evaluated by the REC.)

To the “Details of Study,” one of the required documents that must be presented to the REC, entails an explanation of the “proposed methodology.” Taking the two cited examples as a simple form of illustration, the use of semi-structured interviews would require that the researcher submit his or her methodological procedure for the prior approval of the open and closed questions. (The confusion between “method” and “ethics” becomes apparent here.) Once approved, the proposed model is “frozen” and cannot be revised – unless the research project is once again submitted to REC members. Brazilian standards have indiscriminately imposed on all scientific research the informed consent forms signed by participants in clinical trials. Moreover, the research budget and timeline must also be submitted for approval, which duplicates the evaluation work of research funding agencies or graduate school committees. Not even the pilot phase of a research project can get started without the prior approval of an REC.

These stringencies are incomprehensible and, in the case of studies in our fields, they represent a straightjacket to the conduct of inquiry. The advancement of scientific knowledge in our fields will be jeopardized by these strict regulations. Action research will become infeasible; participant observation and unstructured interviews will be hampered; rigid methodological canons will become a roadblock to free creation, and to the production of social knowledge. And that is not all. It is pathetic to imagine that the very production of a major work like *A aventura antropológica: teoria e pesquisa* – a collection of texts on “adventures” in the worlds of theory and research, edited by Brazilian anthropologist Ruth Cardoso years ago (who hasn’t read it in Brazil, to the obvious benefit of his or her own research?) – would be unthinkable today.² Strictly speaking, the rules

² *A aventura antropológica: teoria e pesquisa*, Ruth Cardoso (Ed.), Rio de Janeiro: Paz e Terra, 1986.

and regulations applicable today through the Plataforma Brasil database would have barred the conception of major research studies that were landmarks in the Brazilian social sciences over the past fifty years, for their quality and soundness. In Brazil the current database should in fact be renamed the “Biomedical Research Platform,” to reflect a scope circumscribed to biomedical topics.

Regrettably, the current standards, issued by Conep, demonstrate a thorough ignorance of, and disregard for, the conditions and procedures intrinsic to research in the social sciences and humanities. Essential to these fields, in addition to the respect for key ethical principles, are the freedom and the right to create, which derive from the “ethics of adventure” and the spirit of craftsmanship that guide research in the behavioral sciences.

In the last few months, the intervention of Anpocs, the Brazilian Association of Graduate Programs and Research in Social Sciences, and of ABA, the Brazilian Anthropological Association, has opened a dialogue with Conep and the Ministry of Health in Brazil, aimed at defining the limits between, on the one hand, the current regulations governing the ethics of research in biomedical sciences (CNS Resolution no.196/1996) and, on the other, the ethical demands of research in the human and social sciences. In this regard, some progress has been made, by delineating the legal and ethical aspects that differentiate the distinct “worlds of research.”

However – and herein lies one of the main purposes of this forum – the creation of an independent alternative to the Health Ministry’s current system in Brazil should necessarily include social science research projects in the health fields, once they are removed from the umbrella of resolutions by Conep/Plataforma Brasil. The social sciences in health are by definition the product of social research. As such, on epistemological and methodological grounds, a distinction between the social contexts of health and the social as “a total social phenomenon” (as the great French sociologist Georges Gurvitch would put it), would be artificial, unthinkable, and indefensible.³

What is advocated here is thus pertinent to institutions, such as public health departments or university programs, that are home to lines of research inhabiting both worlds – biomedical science programs as well as the social sciences: they should have two separate committees, associated to two different, independent, autonomous platforms of research ethics; in this country, these platforms should be renamed the “Biomedical Research Platform” and the “Social Sciences and Humanities Platform”. Researchers must confer with the body responsible for coordinating research within their own institution (which will serve as a consulting, not as an imposing, board); however, they will be free to choose an ethics research committee that they consider more tuned to their own proposals, among the newly created platforms. The adoption of these guiding principles is urgently necessary today, if the worlds of science in Brazil and elsewhere dare to develop free from authoritarian and bureaucratic dictates, which are inconceivable and untenable in the search for scientific knowledge.

Luiz Antonio de Castro-Santos

Professor, Instituto de Medicina Social/
Universidade do Estado do Rio de Janeiro

³ Jean Cazeneuve, La sociologie de Georges Gurvitch, *Revue française de sociologie*, Paris, v.7, n.1, p 5-13, 1966.