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## SCIENTIFIC RESEARCH INVOLVING HUMANS AND EVOLUTION OF ETHICAL STANDARDS ADOPTED BY BRAZIL

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**Abstract:** This article aims to discuss the complexities of the Brazilian debate on research ethics, especially since the 1990s. To this end, it begins with a brief introduction to the context of contemporary bioethics and how its norms and principles provide content and form for approaches to research. It then details the history of the National Research Ethics Commission (CNE) and the evolution of the ethical standards adopted by the National Research Ethics Commission (Conep), as well as the subsequent changes that occurred after the creation of the National Research Ethics Commission (Conep). The analysis is based on documentary evidence provided by official ECLAC documents (the coordinating body of the CNE).

**Keywords:** Social Anthropology; search; ethic.

## INTRODUCTION

The atrocities committed during the Second World War forced the development of ethics for human research. Since Nuremberg, various standards and resolutions have been developed around the world for these practices. In Brazil, Resolution 466/2012 of the National Health Council establishes the ethical and scientific bases for such research. According to Fundação Oswaldo Cruz (FIOCRUZ), the importance of freedom of scientific research and the benefits of scientific and technological progress must be recognized; at the same time, it must be emphasized that this research and its further development are ethical and respect human dignity, human rights and basic freedom.

Ethical research requires respect for the dignity and autonomy of research participants, recognition of their vulnerability and guarantee of their willingness to contribute and continue or not to participate in research through clear, free and informed expression; a balance of interests, individual

or collective, commits to maximizing interests and minimizing hazards and risks, and ensuring that foreseeable hazards are avoided; it must be socially relevant, guaranteeing equal consideration of the interests involved, without compromising its social humanity in the doctrinal sense; finally, it requires the prior approval of the Research Ethics Committee (ZIP CODE).

## BIOETHICS IN BRAZIL

The topic of ethics related to qualitative health research in Brazil has been widely debated by researchers from different areas of Human Sciences and Health Sciences in recent decades. It is not by chance that this debate has intensified since the implementation of Resolution n° 196/96, of the Ministry of Health, as it established concepts and procedures for research involving human beings in Brazil, improving a process that had been unfolding, slowly towards the regulation of research and the involvement of subjects in studies.

Goldin (2006) rescues the history of bioethics and Brazilian research and describes some of the milestones that made it up. According to the authors, there was a lot of discussion about health issues in the 1980s. In the context of the redemocratization of the State, the debate on individual and social rights deepened, and the Unified and Decentralized Health System (SUDS) emerged, whose “control social” is a fundamental element of the State, construction and municipal health. In 1986, the Brazilian Society of Tropical Medicine and the Brazilian Association of Anthropology presented a document to guarantee the specificity of the consulting and research community. Called the “Community Code of Health Rights”, it recognizes in its preamble that censuses are often carried out in developing countries, where citizens’ rights are not guaranteed.

This document appears to be the first to provide for the creation of research ethics codes and committees in Brazil, as can be seen below.:

Art. 9 - All knowledge derived from the investigation must be forwarded to the competent health authorities, this way the results will be used by everyone. In order for the health rights of communities to be observed:

1 - They must be incorporated into the Brazilian Code of Medical Ethics. In the future, this Code may be able to legislate medical practices related to communities; 2 - Ethics Committees must be created in medical schools, hospitals and governmental and private research institutes; 3 - Ethics Committees must be created in Brazilian research promotion and funding agencies, such as the National Council for Scientific and Technological Development (CNPq), Financing Agency for Studies and Projects (FINEP) and Research Support Foundation of the State of São Paulo ( FAPESP), etc.. **(CODE OF COMMUNITY HEALTH RIGHTS, 1986).**

Two years later, the first review of the recently created National Sanitation Commission (CNS) - Resolution 01/88 - proposed norms for health research, the creation of mandatory ethics committees in research institutions in the health area and the use informed consent, this must apply to “studies with minimal or greater than minimal risk”. (Goldin, 2006, p. 22). Investigations with risk “below the minimum” will be exempted from applying it.

However, Goldin stressed that the implementation of resolution 1/88 did not have the expected impact. In 1995, tensions between health-related industrial sectors and difficulties in implementing regulations with universities and research institutes led the CNS to form a working group to discuss the realities of research in Brazil and propose new solutions. The group, made up of members

from various governmental and non-governmental bodies, developed a regulation, and one of the main changes was to expand its scope to all research involving human beings, not just health research. At the end of the process, Resolution 196/96 was promulgated, which defined the creation of a Research Ethics Committee (ZIP CODE), Informed Consent and Research Ethics Committee (CONEP) within the CNS. It was repealed in 2012 by Resolution 466, which took effect in July 2013.

Resolution Number: 196/96, as described in its preamble, incorporates the basic references of bioethics: autonomy, non-maleficence, beneficence, justice and for that very reason, in subsequent years, it became popular both because of its consensus and its dissent. Consensuses that refer to the need and importance of a regulation on research that, based on documents such as the Nuremberg Code, the Declaration of Human Rights and the Declaration of Helsinki, among others, opportunely came to try to prevent abuses of experiments on human beings. Regarding dissent, we find critical bioethical theories - such as, for example, feminist-oriented bioethics - which, according to Diniz and Guilhem, citing Susan Wolf, refer to an indisposition with regard to ideological principles of bioethics:

(1) A preference for abstract rules and principles that disregard individual and contextual differences; (2) Preference for liberal individualism that obscures the importance of groups; (3) Preference for institutional spaces of practical application, such as government, medical schools or hospitals; (4) Preference for isolation in the face of critical postmodern theories (DINIZ; GUILHEM, 2000, p. 233).

According to Diniz (2010), Resolution nº 196 of the Ministry of Health (BRAZIL, 1996) shows a double inspiration: on the one hand, a utilitarian influence (fundamentally,

manifested in the importance of the configuration of “risks and benefits” and the notion of “vulnerability” as guidelines for the evaluation of ethical procedures); and on the other, a liberal influence (explicit in the importance of protecting human rights and the notions of secrecy, anonymity and autonomy of the investigated subjects). It must be noted that the later CNS Resolution N° 466 (BRAZIL, 2012a) maintains such influences, incorporating into the regulatory work the control of the work of the ZIP CODEs themselves and detailing the attributions, duties and responsibilities of research participants and their inspection agents. Among other regulatory definitions, Resolution N° 466/12 presents the conceptualization and guidance of procedures for the free and informed consent process, the risks and benefits of research, the research protocol and the Zip code/CONEP system itself and its attributions and competencies .

In the process of regulating research ethics in Brazil, the creation of Plataforma Brasil (2012b) is still outstanding. In this regard, it is worth considering the description of the objectives of such a platform:

The Brazil Platform is a national and unified database of research records involving human beings for the entire Zip code/CONEP system. It allows research to be followed at its different stages from submission to final approval by Zip code and CONEP, when necessary - even enabling the monitoring of the field phase, the sending of partial reports and the final reports of the research (when completed). [...] The system also allows the presentation of documents also in digital media, providing society with access to public data of all approved research.

Through the Internet, it is possible for all those involved to access, through a shared environment, the information together, significantly reducing the processing time of projects throughout the Zip code /CONEP system (BRAZIL, 2012b).

The excerpt above shows the national unification of research records, the monitoring, by the Zip codes and CONEP, of the entire research process and the access, to society, to the public data of the approved researches. The investment in the values of transparency, control and standardization of procedures, characteristic of evaluation practices (STRATHERN, 2000), are emphasized. It can even be said that the Brazil Platform is not only an instrument for unifying research records, but also for evaluating and regulating the work of the ZIP CODEs themselves. In addition to the brief presentation of its objectives explained above, the initial page of the Plataforma Brasil website presents a quantitative report on the quality of its own operation. It is possible to verify in a table that presents “Zip code in numbers -2013” and “CONEP in numbers - 2013” the number of projects received and issued, the average time of the first opinion and the final opinion, as well as the number of issues issued and of projects in progress.

The transformation of complex situations and scenarios into synthetic categories of measurement and comparability, the indicators, is part of the reform and modernization processes, as well as the generation of *accountability* (MERRY, 2011). The growing use of “certification policies” - that is, the attribution of a seal of conformity to a product, taking into account its production process (RADOMSKY, 2010, p. 16) - could also be included in this scope of reflections, being the Zip codes themselves and, in general, the Plataforma Brasil, spaces for research certification. The development of performance indicators and their public display, in accordance with the certification standards established in this process, give the impression of effective procedures for ethical control and regulation, as well as transparency in regulatory processes. A sense of “ethics”

arises through the agency of the national platform itself. In this case, it is possible to perceive that instruments, committees and regulatory procedures not only ethically evaluate studies and research carried out in Brazil; such technical instruments have an agency in the configuration of the very meaning of “ethics” to be constituted and evaluated.

In addition, the very existence of a national platform significantly called “Brazil” also highlights the constitution of a process of development of the country’s science that has been associated with other regulatory instruments, at least since the late 1990s - for example, the Lattes curriculum system, Capes graduate evaluation reports, the directory of research groups, etc. This dimension makes us realize that the bioethical influence on normative production in relation to science in Brazil is added to modernizing emphases of science carried out in the country. As Fassin (2006) emphasizes regarding his research experiences in France and South Africa, national traditions and world geopolitics are also relevant elements in the configurations of ethical regulatory practices. Fundamentally, this implies considering the regulatory practices of research ethics as political elements for the configuration of authorities, objects and preferred means of intervention, and not as the neutral tools for data management and control.

In Brazil, it can be said that the emphasis on ethical regulation of research is in line with investments in the internationalization of science and, in this sense, the media campaigns on “Science Without Borders” (held from 2012 onwards) draw attention, although presented as a program for the development of national science by sending students and researchers to universities abroad, deliberately excluded, in its initial phases, the areas of humanities and social sciences.

Such exclusion seems to be associated with the deliberate indifference regarding the specificities of such areas of study in force in the regulations of ethics in research, announced by several commentators of such policies - among others, Victora et al. (2004), Fleischer and Schuch (2010). This scenario causes great concern, due to the effects of current policies on the conception of ethics created and evaluated by such instruments. By putting into play a diverse and heterogeneous set of reform projects based on moral configurations that privilege the values of administrative efficiency and control, standardization and monitoring of procedures, as well as new ethics of self-responsibility, calculation and self-management of those involved, a certain sense on ethics is also configured in this process.

It is in this sense that it is argued that regulatory instruments, committees and procedures not only ethically evaluate studies and research carried out in Brazil; such technical instruments have an agency in the configuration of the very meaning of “ethics” to be constituted and evaluated. As the anthropologists Marie-Andrée Jacob and Annelise Riles (2007) said, one of the most evident products of modern ethics is that this domain has to be constantly made explicit and bureaucratically evidenced. All this work is presented as a self-evident good, always loaded with a sense of making things better (JACOB; RILES, 2007). However, this process does not simply imply information control and management: in the logic that associates aspiration and regulation, by instituting verification procedures, such policies produce knowledge taken as “ethical”. That is, a certain perspective on ethics is also configured in this process, associated with transparency and control of certain information.

## TECHNICAL ETHICS IN BRAZIL

In addition to a sense of ethics reduced to transparency and control of information and far from being a configuration that affects only the researcher, the current regulations have effects on the discursive production of subjects: the researcher and the target subjects of the research. The production of regulations that define the relationships between the subjects involved in the research from the a priori notion of “vulnerability” of those who will be the targets of the studies can lead to a disregard of the authorizations of these subjects and also of the very dimension of how such a situation is produced and experienced in particular settings. It is an apparent multiplication and democratization of the forms of research control and of new protocols for this, which can complicate the modes of justification of qualitative research that involves researched subjects and research subjects in interactions of different types. This shift would be welcome if it were not often associated with a kind of disavowal of more classic controls on qualitative research given by the target groups of research and studies, or with an invisibility of particular issues that may be associated with certain domain of phenomena, less evident sides of this process.

An example of this dynamic can be seen in the experience of anthropologist Nei Clara de Lima and her research team, regarding the anthropological study of Karajá dolls, carried out in order to subsidize the request for registration of this cultural reference of the Karajá people as Brazilian cultural heritage. (LIMA, 2014). The research started at the end of 2008 and ended in 2011; fieldwork took place in the village of Santa Isabel do Morro and some adjacent villages (Wataú, JK and Werebia), on the island of Bananal-TO and in the villages of Buridina and Bdè-Burè, in the municipality of Aruanã-GO. As part of the negotiations to carry out the research,

trips were carried out to obtain the consent of political leaders (caciques) in each of the villages where the research would be carried out, in addition to requesting a license for research at Funai and forwarding the project of research to the Zip code of the UFG. However, despite the fact that the studied group agreed to carry out the research, the Zip code of the UFG took a long time to formalize its own authorization, disavowing the Karajá group in this process.

The very definition of vulnerability given “in advance” and associated with certain groups makes it difficult to problematize how this notion is produced, lived and experienced differently in particular scenarios, as highlighted by Braz (2013) in a text on the subject:

In the field that identifies the “research subjects”, in the CONEP’s “cover sheet for research involving human beings”, there is a concern with the so-called “special groups”, which appear, in the very terms of the document, as subjects under 18, people with “mental disabilities”, embryo/fetus, subjects in dependent relationships (students, military personnel, prisoners, etc.) and “others”. In this sense, it is necessary to inquire about the possible effects of this form for the production of these subjects, shall we say, “vulnerable”. Their vulnerability is, by the document, given in advance - either by bodily marks or by social situations seen as crystallized, making it difficult to problematize around the need to understand the ways in which vulnerability, inequality, or even violence, before being universal, pre-cultural or ahistorical data, are always produced and lived in particular cultural, experiential and relational contexts (BRAZ, 2013, p. 34-5).

As Braz (2013) also shows, the requirements of current ethical regulation policies can not only produce in advance the vulnerability of the researched groups, but

also accentuate or provoke vulnerabilities in the investigated subjects. According to Braz (2013), investigations on sexuality among subjects under the age of 18, for example, could subject those investigated to having to receive authorization from their parents and/or legal representatives, from whom they may want to hide this theme. In addition, the age criterion for defining a “vulnerable” population can hide other important markings in the definition and problematization of research universes, such as race, class and sexuality. The author’s reflections aim to problematize the extent to which the characteristics of research on sexuality are contemplated in the current regulations and, in the case of the configuration of the notion of “vulnerability” of certain populations, on the effectiveness of the construction of such a concept detached from its context and production.

Similar issues were also pointed out by MacRae and Vidal (2006) regarding the possibility of reinforcing the stigma that the signing of a consent form can cause among users of illicit drugs, populations living on the street, and other groups whose identity registration, precisely for ethical reasons, it cannot and must not be carried out. In light of these questions about the effects of the type of regulation of ethics in science currently in force in Brazil, it is legitimate to ask whether, in the case of research with institutions or between universes heterogeneously marked by asymmetrical power relations, the current guidelines cannot also privilege the point of view of subjects with greater authority and conditions to objectify their research meanings. After all, who can authorize a research to be carried out within a public institution, for example? The head or president of the institution? As Bevilaqua (2010) has already pointed out, ethics in qualitative research can be considered a multiverse in which many control plans need to be taken

into account, which greatly complicates its consideration.

When considering the proclaimed pluri-ethnic dimension of Brazilian society, the conflicts with the universalizing normative prerogatives of research ethics stand out. If we analyze indigenous conceptions of what is called “childhood”, for example, we will see that it has little to do with modern hegemonic definitions that understand this period from the notions of development and becoming, accentuating its character of vulnerability (SCHUCH, 2014). As anthropologist Antonella Tassinari (2007) has already written, there are a number of differences between modern and indigenous conceptions of childhood:

We found that, contrary to the adult-centric view of Western thought, Indigenous thinking places children as mediators between high-performance cosmological categories: dead/living, men/women, affines/consanguineous, us/others, predation/production. Likewise, contrary to our social practice that excludes children from decision-making spheres, indigenous children are key elements in the socialization and interaction of social groups and adults recognize in them potentialities that allow them to occupy spaces of full subjects and producers of sociability. (TASSINARI, 2007, p. 23).

## FINAL CONSIDERATIONS

Due to the criticism of the processes highlighted above, anthropologists with research in Brazil make a double effort (SCHUCH, 2013a): on the one hand, they produce a “critical engagement” by participating in Research Ethics Committees, they try to adapt the existing guidelines to the specificities of the Social Sciences and struggle to expand the legal terms to encompass specificities of research in the humanities. On the other hand, there is the effort towards a

“reflective refusal” (DUARTE, 2004), through the fight against metadisciplinary guidelines and the serious debate of the main tensions around the subject.

Some movements in the area of Human Sciences were carried out. It is worth mentioning the pioneering creation of the Ethics Committee of the Institute of Humanities of the University of Brasília, in 2008. As the first committee specialized in “social research”, its creation was motivated by the dissatisfaction with the implementation of current procedures and the recognition of the importance of ethical review in the human sciences (DINIZ, 2010). It is noted that “social research” is configured, by the Zip code-IH/UnB, as all qualitative research and/or that adopts analytical perspectives from the Human and Social Sciences. Even with such specificity, it is possible to verify that the notion of “risk”, typical of the biomedical rationality associated with regulatory policies, still significantly marks this domain of intervention on ethics, even in this committee specialized in “social research”. This is because the “minimum risk thesis” is added to the definition of “social research”, to affirm the particularity of research in this area – which, according to the definition adopted in the Zip code-IH, would involve risks similar to those existing in everyday social relationships. Despite such interpellation, the “minimum risk thesis” of social research is opposed to the specificities of research in the biomedical area and it is in this sense that this notion is used by the Zip code-IH, that is, to problematize the use of free and informed consent. clarified in social research.

More recently, since April 2013, based on the mobilization of scientific associations representing the different disciplines of applied Human and Social Sciences, political mobilization efforts have been made against the binding of regulations on ethics in research

in Brazil linked to the Ministry of Health, such as Resolution No. 196/96 and Resolution N° 466/12. The Forum for the Association of Human, Social and Applied Social Sciences was created, as well as a Working Group for the elaboration of a “complementary resolution” to Resolution n° 466/12, which specifies and reinforces the biomedical influences and their centralism in the the terms and definitions of the ethical aspects of research involving human beings. This proposal aims to transform the terms of current regulations, in a scenario of growing hegemony of the biomedical model for defining ethical protocols in research in Brazil.

In the draft formulated by the WG, in addition to highlighting and ensuring that ethics in research in the Human and Social Sciences implies respect for and guaranteeing the full exercise of rights to participants, the draft considers that ethics: “is a human construction, therefore, historical social and cultural” (ABANT, 2014, p. 1). It also considers that the Humanities and Social Sciences have specificities in their conceptions and research practices, insofar as a plural conception of science prevails in them. The draft also defines the very concept of research in the Humanities and Social Sciences:

XIII - research in the human and social sciences: that which focuses on the knowledge and understanding of the conditions, existence and experience of people and groups, in their social relationships, their cultural values, their political ordinances and their forms of subjectivity and communication, in a way direct or indirect. (ABANT, 2014, p. 3).

Finally, from the work developed, it is possible to highlight that such modes of engagement show that there is no refusal of ethical review in Social Anthropology; the search is for an expansion of the terms of the configuration of “ethics” and a work for its political reinsertion. Unfortunately, however,



at the end of January 2015, CONEP formally rejected the draft proposal prepared by the WG established by the Commission itself, creating a very conflicting scenario for researchers in the Human and Social Sciences, who continue to fight for their specificities to be recognized and respected.

In this “fight”, perhaps it would be pertinent to consider the constant need to expand the circle of interlocutors in the debate on ethics: in addition to the participation of the “community” in the Zip codes, making the debate on ethics and research extrapolate the walls of the university. It is also intended,

through this procedure, a certain model of “science” that is more excluding and elitist, at the same time that the disciplines that work with qualitative research can feed on ethical demands that challenge their disciplines. Furthermore, it is important to pay attention to ethics as a contingent, relational dimension and not given by a stable community of professionals and paradigms, but by complex and situated negotiations that involve several interlocutors. It is, in short, the necessary accentuation of the political aspect of ethics in research, which implies complexity and caution in its consideration.

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