Risks, authorizations, and pending issues: a reflection on the CEP-CONEP system from the perspective of the anthropology of health

Riscos, autorizações e pendências: uma reflexão do sistema CEP-CONEP a partir da antropologia da saúde

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Abstract

In this article, we reflect on the normative practices and conceptions established by the CEP-CONEP system, which have resulted in obstacles for research in the Human and Social Sciences (HSS), despite being mostly harmless to the physical, psychological, or social integrity of the participants. These impediments have elicited reactions from researchers in these fields, particularly those in the anthropology of health, culminating in 2016 with the definition of a specific CONEP resolution for research in this area. Based on reflections, debates, and situations raised by our practice as researchers, advisors, members of CEP, and/or CONEP working groups, we discuss how, from different understandings of the notion of "risk" and its typification, and a contractual ideology of the research relationship based on the idea of "authorization," the concept of "pending issues" is produced, a key category in the evaluation by ethics committees. Attempts to establish models for these three categories encounter the complexity involved in fieldwork, which is formed by different actors, with distinct and sometimes conflicting interests, commonly observed in institutions permeated by power relations, especially in the field of health.

Keywords: CEP-CONEP; anthropology of health; risk; pending issue; authority.

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Resumo

Neste artigo, refletimos sobre práticas e concepções normativas colocadas pelo sistema do Comitê de Ética e Pesquisa da Comissão Nacional de Ética em Pesquisa (CEP-CONEP) que tem resultado em entraves para as pesquisas das Ciências Humanas e Sociais (CHS), embora essas, em sua maioria, não coloquem em risco a integridade física, psicológica ou social dos participantes. Os impedimentos suscitaram reações por parte de pesquisadoras/res dessas áreas, notadamente aquelas/es da antropologia da saúde, o que culminou, em 2016, na definição de uma resolução específica da CONEP para as pesquisas nessa área. A partir de reflexões, debates e situações suscitadas por nossa prática como pesquisadora/res, orientadora/res, membros de CEP e/ou de grupos de trabalho da CONEP, discutimos como, a partir de compreensões diversas sobre a noção de "risco" e sua tipificação, e de um ideário contratual da relação de pesquisa pautado na ideia de "autorização", se produz a "pendência", categoria nodal de avaliação dos comitês de ética. As tentativas de fixação de modelos para essas três categorias esbarram na complexidade envolvida no trabalho de campo, quando este é formado por diferentes atores, com interesses distintos e por vezes conflituosos, comumente observados em instituições atravessadas por relações de poder, especialmente no campo da saúde.

Palavras-chave: CEP-CONEP; antropologia da saúde; risco; pendência; autoridade.

Introduction

The conceptions of risk that guide the institutions responsible for the ethical regulation of research in Brazil, since the establishment of the *Comitê de Ética e Pesquisa da Comissão Nacional de Ética em Pesquisa* (CEP-CONEP – Ethics and Research Committee system of the National Research Ethics Commission) in 1996, have historically been informed by biomedical practice and clinical research (Falcão, 2019; Bosi, 2015; Harayama, 2011). This perception has resulted in the relatively regular practice of placing research projects by social scientists in "pending" status, even though most of these studies involve methodologies that are neither invasive nor do they pose risks to the physical, psychological, or social integrity of participants, such as participant observation and interviews. In this scenario, tensions also emerge over the contractual model involving the types of authorization requested and granted by these bodies which, under the argument of protecting the interests of the participants, disregard important sociocultural aspects that permeate Brazilian society as a whole, as well as the particularities linked to certain fields of research and the methodological strategies of anthropology and the human and social sciences (HSS) in health (Víctora et al., 2004; Fleischer; Schuch, 2010; Duarte, 2015).

In this article we discuss how, from different understandings of the notion of "risk" and its typification, and a contractual ideology of the research relationship based on the idea of "authorization," the concept of "pending issue" is produced, a key category of evaluation by ethics committees. Attempts to establish models for these three categories come up against the complexity involved in fieldwork, which is made up of different actors, with different and sometimes conflicting interests, as is commonly observed in total institutions permeated by intricate power relations, especially in the health field. Our intention is not to oppose the evaluation of the ethical aspects involved in research with human beings, but rather to highlight how the argument of ethics can and has been used as a mechanism to control the biomedical area over other fields of knowledge.

To build our argument, we draw on debates about research ethics in general, as well as specific situations observed in our practice as researchers, advisors, members of CEP and/or CONEP working groups. Thus, the reflections that guide this text are anchored in material from our professional practice, whose exemption from evaluation by the CEP-CONEP system is justified based on Article 1 of Resolution 510/2016, in its sole paragraph that deals with cases of non-registration and non-evaluation by the CEP-CONEP system, specifically item VII that justifies the exemption for "research that aims to deepen the theory of situations that emerge spontaneously and contingently in professional practice, as long as they do not disclose data that can identify the subject." With this ethical precept in mind, we did not mention the state or region where the institutions are located, their names or the names of the researchers involved in the situations we analyzed, thus maintaining the commitment to anonymity that the resolution provides for.

Ethical control in (or of?) research with human beings: a brief history

The discussion about the ethical limits of scientific research and its effects on other beings, human or non-human, is an old one. The moral dilemmas surrounding the dissection of corpses for the purpose of research into the functioning of the human body lasted until the 16th century, when it was authorized by the Church. As for research with non-humans, in the 19th century animal protection associations began questioning the use of animals in research (Kottow, 2008). However, it was only in the mid-20th century that emerged a compelling need to formulate standards and codes of conduct for scientific research, especially involving human beings.

With the end of World War II, the medical experiments carried out on humans in German universities, research institutes and Nazi concentration camps were revealed, based on research into eugenics and "racial hygiene," physical anthropology and genetics (Proctor, 1988). Experiments such as injecting dye into children's eyes to change their color, inseminating women with animal semen, purposely infecting people of different "races" with diseases, imposed an ethical imperative on the scientific community of the time in order to prevent these actions from being repeated (Kottow, 2008). In 1947, a court made up of judges from the United States (US) met to judge the crimes of the Nazi doctors. By bringing to light the atrocities committed in the name of science, the trial resulted in the drafting of the Nuremberg Code (NC), a set of ethical precepts for clinical research.

Still mapping out the regulatory frameworks for ethics in research with human beings is the Declaration of Helsinki (DH), launched in 1964 by the World Medical Association. Unlike the NC, which was aimed at judging the actions of doctors carried out during the Nazi regime, the DH was presented as an ethical guide for the future of research involving human beings. Two years after the DH, physician Henry Beecher published the article "Ethics and Clinical Research" in which he analyzed 22 clinical trials carried out in the USA that experimented on prisoners, older adults in nursing homes, children with intellectual disabilities, and newborns, i.e. people who were unable to object (Diniz; Correa, 2001).

The existence of NC and DH and the evidence provided by Beecher's article, however, did not prevent research with serious ethical problems from continuing to be carried out in the US. A striking example was the Tuskegee Study, carried out between 1930-1970, which investigated the effects of syphilis on Black men, deliberately denying them the use of penicillin. Following the public scandal, the US government and Congress set up a national commission in 1974 to identify the basic ethical principles that should guide human experimentation, which became known as the Belmont Report (BR), released in 1978. The principles defined were: (a) the principle of respect for persons; (b) the principle of beneficence; and (c) the principle of justice, which later formed the basis for the development of the Principialist Theory (PT) in bioethics.

PT is based on four principles. The first is autonomy, which states that every human being should be free to decide what is best for them and cannot be coerced into making decisions that harm their interests; the second principle is beneficence, which states that the purpose of the development of science should be to promote the comfort and well-being of human beings; the third principle is

that of justice, according to which human beings are equal from birth and cannot be denied any treatment or assistance because of discrimination arising from their social status, race, or any other factor underlying their identity; and the fourth principle, which follows on from the second, would be that of non-maleficence, which determines the obligation to not intentionally inflict harm on someone.

However, Diniz and Guilhem (2002) emphasized the impossibility of establishing legitimate universal ethical principles that include pluralism among people with different cultures and moralities. The authors proposed recognizing different bioethics that embrace differences and promote tolerance as a requirement for mediating the conflicts that bioethics deals with. These criticisms, raised against the essentializing potential that permeates bioethics, were not intended to defend the non-existence of ethical principles that can be universally shared in relation to research with human beings, but rather their unmediated transposition to different cultural contexts and areas of knowledge. In this sense, social researchers have positioned themselves critically in relation to the pharmaceutical industry's constant attempts to make ethical declarations and regulations more flexible, with the ultimate aim of exploiting the vulnerabilities of the populations being investigated, rather than strengthening their protection (Diniz; Correa, 2001).

As can be seen from this brief historical overview of the construction of regulations and reflections on ethics in research with human beings, they all resulted from concerns raised regarding abuses committed in the practice of biomedical research, some of which caused irreversible and even fatal damage to participants.

In Brazil, the first national regulations on research ethics came into force with Resolution 196 of 1996, drawn up by the *Conselho Nacional de Saúde* (CNS - National Health Council), which established CONEP, the main regulatory body responsible for managing the *Conselhos de Ética em Pesquisa* (CEP - Research Ethics Committees) throughout Brazil. Currently, there are more than 850 CEPs spread across the 26 states of the federation and the Federal District, particularly concentrated in São Paulo.

Resolution 196/1996 was intended to cover all research involving human beings, although it was essentially aimed at clinical and experimental research in the biomedical field. Initially, the resolution was ignored by the majority of HSS researchers, a stance motivated in part by the lack of dialog with the scientific community during its drafting. However, before long, it was possible to feel the impacts of its imposition on our research projects.

Research Ethics Committees in Brazil: anthropology's reactions to bioethical imperialism

The obstacles imposed on HSS research were felt almost immediately by researchers with social research themes linked to the field of health, especially when it required fieldwork in hospital institutions. In this context, health anthropology researchers were the most affected group, and also the most reactive to the regulations of the CEP-CONEP system, questioning its biocentric orientation and protocol-based perception of research ethics (Víctora et al. 2004). On the other hand, researchers in Indigenous ethnology were affected as well, since Resolution 196 stipulated that any research with Indigenous populations should be submitted to CONEP for evaluation.

In the 1980s, the *Associação Brasileira de Antropologia* (ABA - Brazilian Anthropology Association) drew up its Code of Ethics and created an internal Ethics Committee, although the discussion on the subject had already been noted decades earlier. Accustomed to dealing with vulnerable and stigmatized populations, anthropologists were used to discussing ethics in their research and collaborating with government bodies to protect the rights of Indigenous peoples, urban workers, rural workers, and social minorities. The theme chosen by the ABA for the 2000-2002 biennium was Anthropology and Ethics, when the issue was addressed in various activities at the 23rd Brazilian Anthropology Meeting, held in 2002. As a result, an ABA book was published with a series of critical reflections on the way in which research ethics was being controlled by the normative vision of biomedicine, to the detriment of other areas (Víctora et al., 2004).

Since then, together with researchers from other fields, ABA members have been working to promote changes, to the CEP-CONEP system, that take into consideration the specificities of socio-anthropological research. In 2011, the ABA presented a motion during the 35th Meeting of the National Association of Graduate Studies and Research in Social Sciences (ANPOCS), in which it recognized the importance of the evaluation of ethical aspects that Resolution 196 promoted, but drew attention to the fact that its scope was restricted to research in the biomedical field. The motion put forward two proposals: the first focused on denouncing the "anomalous, unjustifiable and unsustainable situation of the subordination of social sciences and humanities research to the aforementioned Resolution"; and the second called for the drafting of specific regulations for the HSS, with the participation of researchers from these areas from the Ministry of Science and Technology, and not from the Ministry of Health (Sarti; Duarte, 2013). The motion was forwarded to the public consultation opened by the CNS to review Resolution 196/1996.

In 2012, Resolution 196 was replaced by Resolution 466. Although the new document did not meet our demands, as it was aimed at all research with human beings and continued to operate with the logic of biomedical research, it did at least provide for the construction of a specific resolution for the HSS, which seemed to finally acknowledge the specificities and autonomy of this field of knowledge. In 2013, a Working Group (WG) was created to draft this resolution, made up of researchers from various HSS disciplines, which resulted in Resolution 510, published in 2016.

As noted by Duarte (2015), one of the anthropologists involved in the WG that drafted the new resolution, it was not easy to achieve. The first draft presented by the WG, back in 2014, was widely criticized by the CONEP plenary. Appropriating the idea of "ethical imperialism," Duarte changes the term to:

> the denunciation of intercultural ethnocentrism in the direction of interdisciplinary ethnocentrism: the HSS are treated as areas of colonization, where any resistance to the new bioethical order seems only to bear witness to a supposed ignorance and unconsciousness—in other words, a 'bioethical imperialism' (Duarte, 2015, p.42, free translation).

In this sense, we think it is appropriate to consider the category of risk that guides the evaluations of projects submitted to the CEP-CONEP system through the lens of the social sciences, since this concept is situated in relation to the sociocultural contexts in which it is defined and is a central part of the evaluations of research protocols by the CEPs.

Risk as a sociological category

Bosi (2015) shows that the concept of risk can be approached from two different perspectives in the field of public health: one quantifiable, linked to probability and biostatistical models, typical of the field of epidemiology; and the other qualitative, referring to uncertainty in which subjective factors and social dynamics are considered in the definition of risk and how it is perceived socially. Bosi stresses how the emphasis on precision, accuracy, and predictability—which guides the definition of risk in epidemiology—obscures the complexities present in the phenomena of health and illness, as these involve individual experiences and social interactions, marked by unpredictability and processes that are impossible to fully measure. In this sense, it is necessary to put the concept of risk into perspective, questioning the rigid and fixed character given to it by the mathematical perspective of epidemiology, in order to understand it as a sociological, polysemic and historically situated category.

In the formation of the social sciences in the final decades of the 19th century, what we understand today as "risk" was not an obvious theoretical issue. In general, risk seemed to be implied in the discussion of prohibitions on social practices and rituals that involved "taboo," and therefore danger and fear in the face of the unexpected, the supernatural or the uncontrollable. In the 20th century, we can cite the book by Mary Douglas (1990) as seminal for more recent discussions on risk. Douglas' theoretical concern was to understand the ideas of pollution, dirt, impurity, danger, disease, lack of control and disorder as elements of a broader symbolic system, which articulates other force-ideas, in opposite

and complementary terms, such as purity, safety, health, control, and order. Every people has their own ideas and meanings for thinking about these categories and modes of classification. The most varied ritualization of cleanliness and dirtiness, purity and impurity are also characterized by their "symbolic charge" and their moral dimension, in the sense of generating societal pressure on people, guaranteeing the maintenance of a social order. For this reason, it is also characterized by establishing controls over the limits, the separations between what (beings, people, objects, actions, thoughts) is understood to be clean, pure, healthy, safe, and orderly and its opposite.

But, what about science and, in particular, the ethics of doing science? Visions of what is dangerous and risky are neither uniform nor homogeneous, not even among groups of specialists (scientists, professionals, and public policy managers). There is a complex relationship between knowledge and ignorance about risks, as they can be potentiated in areas and spheres that someone is unaware of. There is a whole body of theory on "risk evaluation" (risk assessment). However, certain ways of preventing risks for some can also cause risks for others. Thus, "risk acceptability is always a political issue" (Douglas; Wildavsky, 1982, p. 4). Douglas proposes a cultural approach to risk and the collective vision that produces knowledge and consensus about it, i.e. how do people reach a cultural consensus that some risks should be avoided and not others?

Lupton (1999) suggests that the way we understand risks in contemporary Western societies is quite particular due to the constitution of modernity, which has led to specific meanings of what risk is, especially with its concern with technique and control of the physical world. Modernity is based on the premise that humanity is capable of acquiring objective knowledge of the world with rational thought and science. This meant that risk came to be understood in terms of objectivity and technicality, linked to the probability of an event occurring. Thus, it is through scientific knowledge that the possibility of risk can be controlled, since rationality is a determining factor in the understanding of risk. Risk is not just defined as a natural cause *per se*, but is presented and detected through scientifically-based procedures that can be controlled.

Based on the vision of governmental and scientific institutions, the distinction between specialized and lay knowledge about risk suggests that there is a difference between objective and subjective criteria for understanding risk. Thus, technical-scientific knowledge is validated by a culturally and socially dominant position and by the authority conferred on it in the circuits of technical-scientific production. Theories and explanations held by people and social groups who are outside the spheres of production of this form of knowledge end up being characterized as common sense, or simply as ignorance or "lack of information". According to Lupton (1999), this perspective assumes that an uninformed person can make correct decisions, as long as they have rational knowledge about what can be a risk to them. This imposes a unilinear model between the stage of lack of knowledge and the stage in which knowledge is acquired.

However, sociocultural perspectives on risk (Douglas; Wildavsky, 1982) do not differentiate between common sense, lay knowledge, and technical-scientific knowledge, as all are historically constituted and defined by social and symbolic factors. Risk can be thought of in terms of greater or lesser cultural mediation, i.e. whether or not what is understood as risk has the nature, or objectivity, of a real risk or threat.

Notably, the issue of risk coexists with the issue of "vulnerabilities" and they have come to form a specific language that covers the most diverse issues, which shows the dilemmas of contemporary societies in relation to individual projects and collective mobilizations. The idea of vulnerability began to be used more commonly from the 1990s onwards. With it, there is a greater concern with socioeconomic aspects and inequalities, especially, but not exclusively, because social markers of difference must be considered, such as gender/sexuality, ethnicity/race, generation/age. Thus, the idea of risk shifts from an abstract perspective toward one of vulnerabilities resulting from social and economic conditions. Vulnerabilities are therefore more often differentiated, unequal and cumulative (Acosta, 2005), without falling into the

trap that an individualistic idea of risk perception can entail. In this sense, in the field of health, the concept emerges as an analytical alternative that tensions the more rigid perception of the concept of risk, present in the epidemiological approach, although it can also, in practice, be mobilized to reinforce this perspective, as we will see below.

The typification of research: from risk gradation to modulation factors

As mentioned above, the debate on the specificities of HSS research, and its consequences for the ethical evaluation process of this type of investigation, culminated in the drafting of Resolution 510/2016. Article 21 of the resolution indicates the need for another specific resolution to regulate the risks foreseen in social research with human beings, which "will be graded at minimum, low, moderate or high levels, considering their magnitude depending on the characteristics and circumstances of the project, as defined in a specific Resolution on the classification and grading of risk and on the processing of protocols" (Brasil, 2016, free translation).

Six years later, after thirty CONEP WG meetings, comprising over ten researchers who met regularly from 2017 to 2021, the aforementioned resolution on risk gradation was promulgated. The members of the WG were graduates in pharmacy, biology, medicine, engineering, law, psychology, and social sciences, with varying postgraduate degrees, although most of them were from the biomedical field.

Resolution 674/2022 establishes the processing of scientific research protocols involving human beings in the CEP-CONEP system, according to the classification of the research, defined in the resolution as the "process by which the type of research is defined, based on the study design and research procedures," and the modulation factors, defined as the "characteristics of the consent process, confidentiality and/or research methods that may modify the type of processing of the protocol in the CEP-Conep System" (Brazil, 2022, free translation).

Resolution 674/2022 provides for four ways of evaluating research projects, three types of research and two ways of defining "modulation factors," according to Silva (2023), a euphemism for risk gradation. In addition to collegiate evaluation, the traditional way of evaluating research projects, three other new forms of evaluation were added: (1) special collegiate, in specific CEPs, with authorization from CONEP to process research projects that were previously directed exclusively to CONEP; and (2) simplified, without going through the CEP collegiate and with an opinion prepared by a member of the HSS, and (3) express, also without going through the CEP collegiate, involving checking the completion of a specific form. The research was classified into three types: A, B and C, so that it could be processed in the four ways described above: (A) research aimed at describing or understanding phenomena that happened or happen in everyday life, with no intervention in the human body; (B) research aimed at describing or understanding phenomena that happen in everyday life, with physical intervention in the human body; and (C) research aimed at verifying the effect of a product or technique under investigation, deliberately applied to the participant as a result of the research, prospectively, with a control group or not. Finally, fifteen risk modulation factors are defined in the resolution according to the characteristics of the consent and confidentiality process and the research methods. It should be noted that Resolution 674/2022 does not explicitly grade risk.

The CONEP WG created new categories to classify risks—the modulation factors—and set up principles of vision and division of the social world (Bourdieu, 1989)—the types of research, based on their objective, in other words, what the studies "aim" to achieve. One of the most heated debates in the classification process was around the issue of "vulnerability," since one of the modulation factors presented in the first draft of the resolution concerned not only the characteristics of the research methods, the consent and confidentiality process, but also the research participants themselves, often considered "vulnerable populations."

One of the WG members, faced with the proposed risk gradation in Resolution 510/2016, rejected this classification, saying that it would be unfeasible to consider any study conducted in the Rocinha favela as being of minimal risk, since violence is a daily occurrence in this Rio de Janeiro community.

Other members were concerned about research in so-called "sensitive areas," such as those on suicide, depression, and illegal practices, as well as those involving Indigenous peoples. They began to transform their concerns into modulation factors, i.e. every time an element of the research project raised the need to protect the participant, a modulation factor was attributed to it, a phenomenon that converged with the proposal "to identify new forms of harm, sometimes invisible, subtle, but no less harmful" (Bosi, 2015, p. 2680). When one of them presented a research project on breastfeeding, they considered the fact that the study was being conducted in a health unit to be a modulating factor in defining risk. When asked, "What if it was carried out outside the unit?" the answer was: "It depends [silence]. If it's in a poor community, it's also a modulating factor." In other words, the place where the research participant lives, their diagnosis, ethnicity, and income are considered fundamental for assessing a research project from an ethical perspective, pointing to the need to protect them, so studies with people considered to be part of the so-called "vulnerable populations" worried the members of the WG.

Moreover, it was suggested adding the researcher's vulnerability as a modulating factor, using prison studies as an example. One of the members, on the other hand, drew attention to the fact that "things should not be crystallized," that it is not because a person is in a situation of incarceration that they will always be in a situation of vulnerability. The proposal contains the terms "socially disadvantaged person" to refer to so-called "vulnerable populations," as well as "people with diminished capacity for consent" or even with "absent or impaired" autonomy. PT guided much of this discussion about the vulnerability of the research participant as a modulating factor, essentializing the phenomenon based on the principle of autonomy. This group of research project evaluators was haunted by a ghost: the possibility of a researcher concealing the fact that subjects are in a condition of vulnerability. At the same time, if a study is exclusively going to observe children in the classroom, the procedure—observation—would suspend the concern with the type of research participant—child—from the perspective of one of the members of the WG.

The members of the WG were falling into the trap denounced by the country's leading experts on the subject of vulnerability, according to whom "vulnerability is always relational. So, in fact, it would be more appropriate to think of relationships of vulnerability than vulnerable populations" (Castellanos & Baptista, 2018, p. 58, free translation). In this sense, Resolution 674/2022 points to a way out of this deadlock in its Article 12 by finally stating that "the characteristics of the research participant, in themselves, do not constitute a modulation factor."

Authorization, authoritarianism and the production of pending issue

When we consider anthropological research into health and illness, especially that carried out in health institutions and services, we must agree with Heilborn (2004) that the fact that anthropologists work in a multidisciplinary field adds another aspect to the ethical dilemmas in their research. Thus, the field of health places certain constraints on anthropological work. These derive both from the regulations established by CONEP/Ministry of Health and also from the conditions expected by international funding agencies, academic journals, for example, which require that the "research protocol" be submitted to a CEP and include an Informed Consent Form (ICF). Anthropologists such as Duarte (2004, 2015) and Heilborn (2004), despite agreeing with the establishment of research guidelines and regulations, point out that their parameters crucially follow the biomedical model. There are therefore power relations within the disciplinary and scientific field that establish biomedical knowledge as the general parameter to be followed. Thus, knowledge of HSS can be foreign and dubious to practitioners working in this area. How can dialog and agreement be established between "different logics and ethics?" (Heilborn, 2004, p. 58). There are, therefore, impasses when articulating the procedural characteristics of ethnographic research and the "political-bureaucratic determinations" of CONEP, particularly because there is a "pretension to standardize disciplinary fields from a single vision,"

based on the "(worrying) universalism of the health area" (Heilborn, 2004, p. 61, free translation).

These critical issues came to the foreground in the evaluation process of a recently defended doctoral research project. In order to control the anonymity of the actors involved, we will not give details about the location and subject of the research. For the purposes of our analysis, it is worth noting that this was a socio-anthropological study, in which data was collected via interviews and participant observation in a hospital setting and in a patients' association.

The person conducting the study faced a series of impasses, on the one hand, characteristic of the bureaucratic process for carrying out her research and, on the other, originating in the societal dynamics surrounding the process itself, which is not simply technical, but also political-moral in terms of the disputes over the definition and understanding of what is effectively "ethical," and in terms of the hierarchies between academic knowledge in the scientific field. In relation to ethics, it must therefore be recognized that it is not about a consensual meaning and value, as there is historical and social relativity regarding its definition and what its moral sphere consists of, whose limits, rather than being abstract, actually expose a diversity of perspectives and conceptual heterogeneity (Figueiredo, 2004) and thus tensions, antagonisms, and political decisions about what can or cannot be done in research, depending on the sciences in question.

Before registering her research on the Plataforma Brasil (PB), the person conducting the study sought advice on the documents to be attached and the information that would be needed to support the acceptance of her project. At the same time, she also talked to professors, including the one who was supervising her, but also fellow students in her postgraduate program, who had previous experience in this process. She also sought out the CEP that assists researchers in these processes at her university, from which she received careful clarification about the documentation and filling in the forms in order to avoid her project being placed as "pending." The person conducting the study successfully obtained, after reasonable negotiation of what she intended to do, the consent form from the two institutions where participants would be taken for the research and participant observation would be carried out.

Strictly complying with the request for documents, the project was approved by the university's CEP on its first submission and forwarded electronically to the hospital's CEP. The person conducting the study also forwarded the Term of Authorization for the Use of Patients' Documents to the CEP, which would allow her access to the patients' files and medical records, although this term was optional for the researcher if he intended to study the documents. The first response came from the hospital's teaching and research manager, who approved the documentary research, but final approval from the Ethics Committee was still needed.

Another document was also submitted, the Informed Consent Form (ICF), which for the university's central CEP official was the main reason for "ethical pending issues." Based on a model typical of biomedical research, it was necessary to consider and point out in this document the "foreseeable risks," the "procedures that could cause discomfort to the participant," and the "measures that the researcher will take to mitigate them." The person conducting the study specified that the research participant might experience some "emotional discomfort during the interviews" and would therefore be advised to seek psychological assistance from the university.

When analyzing opinions on research projects from a university's CEP, Ferreira (2022) showed the large number of pending issues that prevented the research from starting. In the case of the study we are focusing on, the hospital's CEP opinion justified two pending issues in the research project that the person conducting the study had to resolve within thirty days in order for it to be finally accepted, one of them related to the writing of the ICF. The second pending issue, which we want to reflect on, required the project to include a member of the university hospital's outpatient clinic as a participant in the research team. The doctor who ran the clinic had previously signaled his interest in co-authoring any articles that might be published. The "pending issue" caused strangeness, as it involved the inclusion of a doctor in the anthropological research of a

doctoral candidate, whose end product would be a thesis and did not involve a mutual scientific research project.

The person conducting the study responded on time to the hospital's CEP requests, pointing out that the inclusion of a doctor as a member of the research team created a paradox for the project, as there were differences in the objectives and methodologies of social and cultural health research compared to biomedical research aimed at clinical results in humans. In addition, she pointed out that the doctor in question was part of the group of interlocutors to be interviewed because, above all, of his unique and socially relevant position in the societal dynamics between doctor and patient in a health service, which would compromise the sense of methodological objectification in the social sciences. There was also a serious ethical dilemma in having as a researcher on the team the very doctor who attends to users of an outpatient clinic where he himself would be the health professional responsible for their treatment. In this way, the "pending issue" was especially complex, as it meant the need for supervision by a doctor, in a key position in the relations of authority and power in a hospital setting, of a doctoral candidate in a field other than his own, the social sciences, which highlights the hierarchization of scientific knowledge, even within the same university, legitimizing one area and subordinating another. The person conducting the study added in her reply that she no longer intended to carry out documentary research on the service users' medical records, restricting her research to observing consultations.

The CEP's final opinion stated that the ICF had been accepted after the requested modifications, but the project was definitively rejected, suggesting that it be resubmitted to the ethics committees. According to the opinion's justification, the rejection was due to the fact that there was no doctor from the service responsible for access, safekeeping, and ethical care of the data contained in the patient's medical records, even though the response to the first opinion had already emphasized that it was no longer intended to consult the medical records.

At the same time, there was also a turnaround in the contacts previously made by the person conducting the study with the doctor who demanded his participation as a "member of the research team." The friendly relationship witnessed in the preliminary stage of the investigation deteriorated to the point where the doctor distanced himself from her, directly affecting and compromising her research for fear of possible interference by this professional with the patients who would be interviewed and who had long-standing relationships with this doctor, due to their health condition. The research was redefined, taking into account the long time taken to prepare and process the project before the CEPs, leaving aside ethnography in the health service, which would have been ideal for understanding the interactions and meanings of the people treated there, their families, and the health professionals.

One wonders how difficult it is for health science researchers to share the social space of a hospital or health service with social science researchers. This also shows how the reasonableness of the pending issues and the investigation of the risks of research that is submitted to a CEP expose more the discomfort and disputes over the credibility and legitimacy of qualitative research in the social sciences, such as anthropology, than, in fact, a concern for the safety of the participants or the ethical aspects of the study. In this specific case, which unfortunately is not an isolated case, the project was not approved due to the abuse of institutional power by a professional who demanded to be included as part of a doctoral research team in an area completely different from his own and to which he was not going to contribute by capturing the data, analyzing it or even writing the thesis. According to Haraway (1995), the objectivity defended by researchers in certain areas of knowledge serves, above all, to hide the effects of power relations and hierarchies that differentiate certain types of knowledge from others.

Unfortunately, our experience as researchers, advisors, and members of CEPs has shown us that this was not an isolated event. What was at stake in the case we analyzed is the authority and hierarchy of power that takes place in the CEP of a hospital (where there is no social scientist) in relation to the acceptance and demands made on HSS research. However, there are also a significant number of pending issues with projects in our field, which

reflect the poor interpretation of the resolutions created by CONEP, the low diversity of training areas and the lack of adequate training for members of CEPs, especially those in the health services, not to mention the current authorization model, which comes up against power relations within health institutions, but also in public security institutions and private companies that are resistant to having their practices investigated.

The protocol view of the CEP-CONEP system has allowed HSS research to be put on hold for the most trivial reasons, which have nothing to do with the ethical aspects of the research. To cite a few personal examples in which our research has been placed on hold, we have everything from the absence of the supervisor's cell phone number on the ICF (since she was not the researcher responsible for the study registered with the PB) to the requirement that a study aimed at people with chronic hereditary diseases be limited to "a specific disease" in an obvious interference with the research objectives, as well as the mistaken requirement for a signature on the cover sheet of the funding agency that provided a post-doctoral scholarship, understood by the project rapporteur as research funding and not the researcher. In the latter case, CONEP had to intervene to get the project released, which resulted in a four-month delay in starting the research at a health institution. In none of these examples was the situation itself (absence of a telephone, delimitation to a disease, scholarship) related to the ethical aspects of the research, and even less did it pose a risk to the participants.

Final considerations

Pointing to the need to reformulate the ethical regulation of HSS research, Bosi (2015) proposed the idea of "potential harmfulness" instead of "risk potential." The author argues that harmfulness indicates a "quality" and not a probability, bringing the idea of risk closer to a qualitative perspective, without semantic loss since it still points to the potential harm that research with human beings can produce, but which cannot always be measured and quantified. In proposing an alternative nomenclature for defining risk in social health research, Bosi (2015) points to the challenge that researchers still have to face in building an ethical framework that considers the theoretical and methodological diversity of the field of HSS. The recent approval and sanctioning of bill 6007/2023, which weakens the protection of research participants and was criticized by CONEP itself, shows us that the challenges continue and new responses need to be built collectively.[1]

Anthropology, by the nature of its research practice, has always been based on negotiating with the subjects under investigation. Being accepted by the group and building relationships of trust with them is a fundamental condition for successful ethnographic work. In this process, we are called upon to establish agreements, assume duties and ethical commitments with our interlocutors. Obviously, we are not unaware of the discipline's colonial past and its implications, nor of the fact that initially well-intentioned research can result in writings that expose participants to embarrassing situations in front of their own group, if ethical reflection is not constantly exercised. However, it is necessary to better outline what effective protection of the rights of research participants means, since this legitimate argument can be used for practices of abuse of power and control over our research, especially in official health environments, as in the cases analyzed here.

We therefore believe that the ethical evaluation of research with human beings should be a constant parameter in all areas of knowledge. However, it cannot be transformed into a mechanism for controlling one area over others under the excuse of protecting participants from risks whose definition is intended to be objective and universal, when in fact it is anchored in assumptions that guide biomedicine, itself a cultural system that conforms to a certain worldview in which, unfortunately, the recognition of human diversity and the plurality of knowledge does not seem to be properly contemplated.

1 For more details on the creation and approval of this bill, see the article by Castro and Falcão in this dossier.

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Contribution of the authors

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