

Ethics in social sciences researches: regulation, scientific practices and controversies*

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Abstract

This study results from the mapping, done by means of the analysis of documents and news available in files or at the web, of scientific controversies related to the regulation of the ethics in research with human participants in Brazil. Thus, it presents the controversies related to the regulation of ethics in research with human participants in Brazil, since the implementation and operationalization of bioethics principles with the Federal Resolution 01/1988, and the successive legal changes over time till the visibility of the controversies in relation to the Humanities, Social and Social Applied Sciences (CHSSA). Later, it will present the controversies resulting from that measure and the unfolding of the public debate between CONEP and the actors of CHSSA present at the Human Sciences Work Group till the advent of the Resolution CNS 510/2016. Finally, it will present the following specificities of the research in human and social sciences and their implications to the ethic dimension: argumentative, relational and subjective logic; transparency; vulnerability, and protection of the participants. The conclusion is that the ethic dimension of the research is not separated from the methodologic dimension of each field of knowledge. Besides, it was verified that the alignment of the researchers in human and social sciences in the net of the ethic regulation is fragile.

Keywords

Research ethics – Ethical regulation – Social sciences.

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Introduction

The CEP/CONEP System, the Human Participants Research Ethic Committee (CEP), the National Commission of Research Ethics (CONEP), the Resolution 196/1996, the Resolution 466/2012, the *Plataforma Brasil* [Brazil Platform], and the Free Prior Informed consent (FPIC) – TCLE in Brazil – are constitutive terms in Brazilian research today. But which controversies were involved in its development and implementation?

We adopted in this study the controversies cartography approach, that can be defined as a set of techniques for exploration and visualization of the questions that involve the contemporary sociotechnical debates, before they were established. We considered as controversies those situation in which the actors are not consensual or when they have some kind of agreement is about what they did not agreed about (VENTURINI, 2010).

We have analyzed, firstly, *primary* documents, such as speeches, recordings (audio/video), folders, regulations; and the those classified as *secondary*, such as reports and notes from scientific associations (GIL, 2002). However, in order to expand the access to the maximum of information regarding the action of the actors involved in the regulation of the ethics in research with human participants, we have chosen to look for inscriptions of the actors' action in order to describe the formation of the chosen net. Thus, the *locus* chosen for the visualization of those inscriptions was the internet. According to Costa (2014, p.31), for the construction of a controversy map, the internet is considered a proper environment since the actors' actions involved "leaves traces recorded and filed, though not always accessible". Those traces are the "remains of an action carried out by a given individual in the cyberspace" (BRUNO, 2012, p. 687)².

In the first half of the text, we will present a brief history of the regulation of ethics in research with human participants in Brazil. We will emphasize the elements of the recent controversies around the construction of a specific regulation for the Humanities, Social and Social Applied Sciences (CHSSA). At the second half, we will list a few ethic themes currently open in that debate, especially for social sciences.

Regarding the actors of the regulation of ethics in research with human participants, we have chosen those who have participate of the collective that involved researchers of the humanities, social and social applied sciences, especially those involved in the work group together with CONEP and its members, work in such a way that they have produced effects in the course of the situation, deviating it and creating bounds inexistent before, changing in some way the elements involved (LATOURET, 2012). We sought to identify the *intéressement* devices, considered as a set of actions by which an actor tries to impose and stabilize the identity of other actors in order that they meet his initial goals, strengthening the bounds created (CALLON, 1986). That means there is an active posture of production and displacement of interests between the people, aiming at gathering and enlist allies in a network of associations, in the case analyzed here for stabilizing the biomedical perspective of the ethical dimension.

The need for regulation of the ethic in scientific research has a long history marked by episodes of practices violating human rights and life, both in states of exception, as the

²- Tradução.

Second Great War, both in democratic periods, both in Europe and in the United States of America. In face of the constant bad examples, the concept of bioethics was developed, being considered the “ethics applied to health and research with human participants issues” (GOLDIM, 1997, w.p.) The term bioethics is attributed to the American researcher Rensselaer Potter, when he, in 1971, used it in its work entitled *Bioethics: a bridge to the future*. The history of the regulation of ethics in research in Brazil is influenced by that international debate.

Configurations of the regulation of ethics in research with human participants

We have identified three great configurations on the construction of the regulation of ethics in research with human participants in Brazil, which are not successive stages in time, but that are interwoven: implementation; visibility of the controversies regarding Humanities, Social and Social Applied Sciences, and the overcoming of the lack of legislation strict sense. In that paper, we will deal with the first and second configurations:

1) Implementation configuration

The regulation of the scientific activity that involves human participants, aiming at providing conditions of imposition and operationalization of ethical principles, has begun in Brazil in 1988, when the National Health Council (CNS) of Ministry of Health edited the Resolution nº 1, which regulates the discussion, reaffirming *the Declaration of Helsinki* and the *International Guidelines* (HOSSNE, 2005).

With the edition of Resolution nº 1, we realize that the initial intent of Ministry of Health was compelling the researchers from health area to adopt new postures in the conduction of their researchers, obliging them to create Internal Ethical Committees for the revision of research protocols, in all Brazilian institutions that carried out research in health area.

According to Goldim (2006, p. 21), the Resolution 1/1988 had an “extremely integrating and updated vision for the time”. However, it did not have the impact expected, due maybe to the fact that at the same time the attention was headed towards the construction of the Brazilian Unique Health System (SUS), or for fact that the documentation of the informed consent was not yet incorporated to the research practice or, even, for the majority of the institutions did not implement the Committees as determined (GOLDIM, 2006). In front of that scenario, the National Health System/ Ministry of Health promoted a abroad revision of the newly-conceived net, and for such, has constituted an Executive Work Group in charge of reviewing and updating the Resolution 01/1988 (BRASIL, 1995). What stands out in the revision process of the rule is the figure of Willian Saad Hossne, by promoting actions in the attempt of overcoming the existent controversies.

The first controversy involved the scope of the regulation by extending its incidence beyond the health area, for the work group understood that the research involving human participants was not made exclusively by physicians. Therefore, the new resolution should be applied to the health aspect of human participants, and for such, it was essential to

expand the number of knowledge areas in the formulation of a new guideline in order that the concept of health was beyond the health area (HOSSNE, 2005).

In the revision process, the Work Group foresaw the figure of “social control” over the scientific research (HOSSNE, 2005). With that aim, the Committees for Ethics in Research with Human Participants (CEP) reappeared, that had to have necessarily in their composition, at list, one “users’ representative” (BRASIL, 1996). The term user has a broad interpretation, covering multiple collectiveness that benefit from the work developed by a research institution. Thus, the users’ representative, according to the CNS Resolution 240/1997, are “people able to express points of view and interests of individuals and/or groups subject to research of a given institution and that are representative of collective interests and diverse publics”³ (BRASIL, 1997, p. 1).

The controversy regarding the acknowledgment of specificities of other knowledge areas has been present from the beginning. As an attempt to overcome the lack of acknowledgment, complimentary resolutions were edited for the areas of: new medicine (Resolution CNS 251); foreigner cooperation (Res. CNS 292); human reproduction (Res. CNS 303); indigenous people (Res. CNS 304); genetics (Res. CNS 340); multicenter studies Res. CNS 346), and biological databases (Res. CNS 347). Finally, in order to overcome the argument centered in the excess of bureaucracy and slowness of the evaluations, Hossne (2005) presents as the solution the decentralization of the system, transferring to the Ethic Committees the task of analyzing the ethical aspects of the research protocols, attributed before exclusively to the National Health Council.

Aiming at overcoming all the resistances mentioned and implementing effectively a system of evaluation of the ethical aspects of the research, the National Health Council (CNS) formalized the Resolution CNS 196/96 that brought up two new actors: the National Commission for Ethics in Research with Human Participants (CONEP) and the Committee for Ethics in Research with Human Participants (CEP), making the latter leave the supporting role it had when the Resolution CNS 1/1998 was published.

At that time, was created the National Information System on Ethics in Research with Human Participants (SISNEP) that consisted in an information system via the internet, and that aimed at promoting and facilitating the record of the researches, the guiding on the processing, the monitoring and the elaboration of a database (BRASIL, 2016a). It also sought to offer agility and transparence to the scientific works submitted to the CEP/ CONEP System (HARAYAMA, 2011). Once recorded along SISNEP, the project received a unique number that corresponded to the Certificate of Appliance to Ethical Appreciation (CAAE), whose function was identify the project at the SISNEP itself, to the CEPs, to the CONEP, and to the journals of scientific publication or congresses (BRASIL, 2016a). Thus, obliging the research to integrate the net, aligning the interested in that net, CONEP approached the publishers and fostering agencies making them to bound the provision of resources and the publication of the researches’ results to the presentation of CAAE.

3- We cannot confuse the users’ representative with the *research participant figure*. The term *research participant* was inserted with Resolution 196/96 and refers to people who voluntarily accept to be part. The research participant, until the publication of Res. CNS 196/96, was designated by the terms *subject of the research* and *volunteer*. *Users’ representatives*, in turn, are people nominated by specific entities, usually the Municipal or State Health Councils, to represent the points of view and interests of the individuals and/or groups that will be the research participants.

In 2011, CONEP replaced the SISNEP with the *Plataforma Brasil* [Brazil Platform], an online tool developed for the record of researches, aimed at the general public and with the objective of aggregate more security to the record and monitoring of the researches (CONEP, 2011).

The artifices and devices of *intéressement* developed along the implementation of the system of ethical revision of the projects led to the visibility of the controversies regarding the humanities, social and social applied sciences (CHSSA).

II) Configuration of the visibility of the controversies regarding the humanities, social and social applied sciences (CHSSA)

The publication of Resolution CNS 196/96 set up a new moment for Brazilian regulation. CONEP and the CEPs have been diversified in their composition in order to prevail the equity and universality in the background of its members, respecting the rule that determines that it could not have more than a half of member belonging to the same profession (BRASIL, 2013). The progressive decentering, based on the transference of attributions from CONEP to the CEPs reduced the time needed for the processing of the analysis of the research projects and complimentary resolutions were elaborated to normalize special thematic areas in order to observe the methodological diversity (MARQUES FILHO, 2007), without, however, respond to all critics regarding the lack of scope.

The Resolution CNS 196/96 brought several ethical and methodological dilemmas by expanding the scope of the regulation for putting in its normative body the expression “any knowledge area” (BRASIL, 1996, III. 3). That is, the obligation of ethical evaluation was extended equally to the researches developed in the field of human and social sciences (DUARTE, 2015).

The imposition for the utilization of *Plataforma Brasil*, developed to respond to the Resolution CNS 196/96, to all researches involving human participants, independently of knowledge area, gave broad visibility to the non-acknowledgement of the specificities of the researches developed in the area of human and social sciences. The questionnaire regarding the basic information of the project is the base for the appliance to *Plataforma Brasil*. We can see there evidences of how the methodological guidelines of that questionnaire do not meet the needs of CHSSA researchers. For example, after the identification of researcher in charge of the research and of its team, there is a requirement of obligatory fulfillment of the field related to “study design”⁴, a common term for natural sciences, but that does not fit into the approach of CHSSA researches, or the obligation of presenting a study hypothesis.

In front a scenario of criticism from CHSSA researchers regarding the inadequacies and interferences of the existent regulatory system, CONEP played an important role for the maintenance of the sociotechnical network, and among its actions, has designated a Work Group for the revision of the Resolution CNS 196/96. In that revision process,

4 - According to the *Research Project Submission Manual*, provided by CONEP (PLATAFORMA BRASIL, 2016, p. 15), the “study design concept involves the identification of the type of methodological approach that is used to answer a particular question, implying thus, the definition of certain basic characteristics of the study, such as the population and sample studied, the unit of analysis, the existence or not of direct intervention on exposure, the existence and type of follow-up of individuals, among others”.

in 2011, a public consultation was promoted, and resulted in the presentation of 1,890 suggestions that were forwarded to the 1st Extraordinary Meeting of the Committees for Ethics in Research (ENCEP)⁵ whose slogan was “Updating to Strengthening” and aimed at “the revision of the main points of Res. CNS 196/96 questioned by the public consultation” (BRASIL, 2012b).

At ENCEP was evinced the need to produce specific resolutions for CHSSA areas, without harm to the Resolution CNS 196/96. Thus, as a result of ENCEP was published a proposal for the Resolution 196/96 – 2012 version (SBPPC, 2012), and, in 2012, was approved by the National Health Council the current Resolution CNS 466/2012 (BRASIL, 2012a).

For Duarte (2015), the reason that led CONEP to approve a new resolution was the pressure exerted by the scientific associations, among them those of anthropology, psychology, and social service, which have pronounced themselves formally against the unrestricted appliance of Resolution 196/96. However, yet according to the author, the new resolution was elaborated still focused on biomedical sciences, and contains an article that determines the elaboration of a complimentary resolution related to human and social sciences, thus, CONEPE could not align all the interested, so the controversy was still open.

The publication of Resolution CNS 466/2012 rendered even more evident the controversies regarding the revision of ethics in research in relation to the researchers working in the area of CHSSA, showing the failure of the CONEP’s *intéressement* politics, since the process⁶ exposed the limits of the system in front of the non-biomedical specificities and the need to change the way how the ethical relation is established among the knowledge areas, at the institutional and formal dimensions in the dynamic of the CEPs, since those committees constitute a form contingent of answering ethical questions put by the scientific research as an ethical doing (BARBOSA; CORRALES; SILBERMANN, 2014, p. 485).

By aggregating CHSSA researchers aiming at avoiding the strengthening of a group contrary to CEP/CONEPS System, in July 2013, CONEP organized another work group to elaborate the text of a specific resolution, which was named by the scientific community as *GT-Pesquisas em Ciências Humanas da CONEP* [WG-Human Sciences Researches of CONEP] or only GT-CHS whose characteristic was being the first work group which was not limited to members of CONEP (GUERREIRO, 2016b). According to CONEP (2014), the plurality of formation of GT-CHS’ members aimed at providing the meeting to the mission of elaboration a new rule that respected the paradigmatic and theoretical-methodological diversities of the humanities and social sciences, and maintaining the focus on the promotion and protection of the human rights and the fundamental freedom of the research participants.

5- Information in the preamble of Resolution 196/96, version 2012 (SBPPC, 2012).

6- Barbosa, Corrales, Silbermann (2014) talk about the process of revision of Resolution CNS 196/96 that culminated in Resolution CNS 466/2012, considering that this made the controversies about the ethical review of research in the humanities and social sciences more evident CEP/CONEP System.

In summary, the questions debated by the CHSSA researchers can be grouped as follows: the lack of dialogue between the presuppositions of the research projects and the ethical evaluation system and the defense of the specificities of the research in the CHSSA areas; the difficulty of establishing a unified representation of vulnerability and risk and the lack of effective representation at the ethics committees. Primarily, we have the debate regarding the presumption of a unique model for ethical evaluation – biomedical – to regulate the ethics in research in all knowledge areas, forgetting the methodological specificities of each area. For those of CHSSA, there would not be a denial of submitting projects to a system of ethical revision if it was capable of dialoguing with its disciplinary and methodological presuppositions (DINIZ, 2008) keeping in mind that the CEP/CONEP System was not intended to the particularities of CHSSA (DINIZ, 2013).

In the debate related to the presumption of a single model, the ways the knowledge areas conceive the scientific work, evincing the difficulties of reaching a standardized rule of conduct for the researchers.

[...] showing the limits and consequences, for the investigation in social sciences, when a council defines that the model for protection of the subjects involved in the biomedical research will be the model to be submitted and sealed for all other forms of investigation involving human participants: when the formal (or bureaucratic) process inside the “online platform” becomes the starting point of the research, relegating to the background the contingencies of the investigation process, proper to the substantive negotiation and to the construction of confidence relationships with the research subjects, for the entrance in the field; when there is a reluctance in accepting the historically constituted specificities regarding the methods and the techniques of research in human and social sciences; [...]. (GRISOTTI, 2015, p. 160).⁷

The CEP/CONEP System tends to reproduce the logic of the researches in biomedical sciences. Thus, they turn the committees into loci of methodological evaluation of the projects, as Silva (2017) puts, disregarding that the stage of ethical evaluation of the projects is posterior to the evaluation of other organs of the research community, that is, methodologically the project is already validated.

The second question is related to the treatment given to the risks and vulnerability for, according to Diniz (2013), those were thought for situation involving essentially questions of the biomedical field in which the main example would be the test of a medicine and that lead to the a definition of risks and vulnerability incoherent to the other researches with human participants.

As a possible cause for the adoption of a single model for protection based on the biomedical standard, is denounced the question that deals with the composition not effectively multidisciplinary of the committees. As Diniz (2013) puts, in an oral interview, it is worth questioning which the real composition of the CEPs in terms of “methodological experience and of the look those participants have on the research in human and social sciences” beyond the work in the health area.

7 - Tradução.

Despite the discordances of the Forum of Humanities, Social and Social Applied Sciences (FCHSSA)⁸ regarding the CEP/CONEP System, the former accepted to participate in the GT-CHS and, along with the representatives of CONEP, Ministry of Health and other associations which did not have a seat in GT-CHS, but lived together, for example, in the Work Group for the Humanities and Social Sciences of National Scientific and Technological Council (CNPq), it started a “careful and reflexive [process] in order to combine the needs of a very broad and diversified field”⁹, longing for a dialogue with CONEP that could be fruitful. However, it was evident that the role of GT-CHS was limited to the emission of suggestions, with little decision force (SOCICOM, 2014). As a result of the discussions, in 2014, GT-CHS presented in an assembly of CONEP a minute of resolution. In response to the minute, CONEP’s collegiate informed that its understanding was in the sense that the minute presented was more focused in the defense of the researchers’ freedom than properly in the defense of the research’s participants and that it should pass through adjustments and amendments before being sent to public consultation. They highlighted as arguments the need of emphasizing the complimentary character of the new norm, and not the creation of a parallel evaluation system (VENÂNCIO, 2015).

As a reaction, the GT-CHS sent an Open Response Letter to the CONEP’s Letter, making it clear its positioning regarding the impossibility of dialogue with CONEP’s collegiate and emphasizing the illegitimacy of CEP/CONEP/CNS/MS System to control the ethics in human and social sciences researches, as well as the unethical character of CONEP by obliging the ethical proper of CHS researchers to be submitted to the principles and methods of biomedical research (GT – CHS/CONEP, 2015).

It came to a crucial point the impasse existent between the positioning of CONEP and the GT-CHS’s: 1) CONEP insisted in the complementarity of the specific resolution to be created, emphasizing that the submission procedures of CHS projects should respect the same process of the projects with bioethical values, thus, the minute created by GT-CHS could not be accepted for it would create a parallel system ; 2) GT-CHS understand that the complementarity of the form as presented by CONEP implies subordination and disregarding of the specificities of the knowledge fields.

In order to push the approval of the minute such as presented by GT-CHS, the CHSSA researchers, their associations and FCHSSA have mobilized and consubstantiated a petition of support to the minute of the specific Resolution addressed to the National Health Council considering the broad acknowledge of the principles and procedures discussed by the CHSSA community all over the country (CHANGE.OR, 2016).

On May 24, 2016 was published, in *Diário Oficial da União* [Union’s Official Bulletin] the Resolution n. 510 that says about ethics on Human and Social Sciences researches with the modifications thought pertinent by CONEP’s Council, raising dissatisfaction in some researchers due to the partiality it met FCHSSA proposal.

One of the neuralgic points in discussion is the risk classification, intimately associated the definition of vulnerability of the research’s participants. In the model

8 - Created in 2013 by the humanities, social and applied social sciences associations.

9 - Tradução.

of ethical evaluation applied by CEP/CONEP System, the treatment of risk followed a single criterion based upon the principles of biomedical researches, as exemplified in the researches with medicine tests in which the participants' interests and the pharmaceutical industry's interests are in dispute (DINIZ, 2013). In order to overcome the impasse regarding the risk, GT-CHS have elaborated the rules that would guide the definition of the risks or the knowledge area it was designed for. In the proposal elaborated, the risks would be classified in minimal, medium and high and, according to its classification, the process in Plataforma Brasil would be differentiated. It is worth mentioning that this proposal for defining the process of ethical revision of the research according to the risk involved in it had already been divulged by CONEP by means of its coordinator Jorge Venâncio in his speeches and interviews.

The final text that has resulted in Resolution CNS 510/2016 has not been manifested regarding the form of risk evaluation for human and social sciences and the demand for typification for the different methodologies would begin to be coordinated by the Accreditation Work Group (VENÂNCIO, 2015).

The prohibitions to the draft submitted by the GT-CHS, articles 18 to 24 (risk classification), 26 to 31 (risk-based processing), 34 (equal composition of the full members between the Humanities and Social and Biomedical Sciences areas) and 36 (application of the specific Resolution after the elaboration and approval of a specific form for the CHSSA), were understood as the exhaustion of the debate process with CONEP¹⁰.

Advocating the need for another review system for the CHSSA areas, FCHSSA demanded, as its initial and primary objective, the formation of a Research Ethics Council within the extinct Ministry of Science and Technology and Innovation (SOCICOM, 2014). Another possibility would be the creation of another type of autonomous and independent system, with the elaboration of a code of ethics in research in CHS via the CHS Association Forum or codes of ethics elaborated by each association. In the latter option, there would be an association document for each area and the review process would be done by its own committees, speeding up the procedure and meeting the specificities (MAINARDES, 2016).

Another aspect is that GT-CHS has exposed the consequences arising from the obligation of the Education Institutions and Institutes to submit the projects of scientific initiation and final course assignment to ethical review as such requirement tends to compromise such experiences given the time required for the process until the projects are approved. This fact would cause the researchers at this level of study to opt for monographic or theoretical studies rather than studies whose methodologies worked with human participants. In the draft submitted by the GT-CHS there was a suggestion of non-obligatoriness of the ethical review for scientific initiation projects, not accepted by CONEP.

The Plenary of the National Health Council approved Resolution CNS no. 510 with the following words:

10 - Information gathered from the Minutes of the Meeting of the Forum of Scientific Associations in the Humanities and Social Sciences Area, held on February 11, 2015 at the Brazilian College of High Studies / Federal University of Rio de Janeiro.

Article 1st: This Resolution deals with the rules applicable to research in Humanities and Social Sciences whose methodological procedures involve the use of data obtained directly from the participants or of identifiable information or that may carry greater risks than those existing in daily life, as defined in this Resolution. (BRAZIL, 2016b, p. 1).¹¹

With the publication of the resolution, the debate was directed by CHSSA researchers in order to delimit the advances achieved and identify the necessary overcoming (GUERRIERO, 2016b; DUARTE, 2016). Advances in Resolution CNS 510/2016 include: 1) fair composition of CONEP and participation of CHS members in the review process, requiring reporting of CHS projects to members with expertise in this area (art. 26 and 33); 2) the recognition that scientific merit should be evaluated by the competent authorities, and the CEP/CONEP System should keep the focus on the protection of research participants (art. 25). This is an aspect that needs to be consolidated in the ethics committees' evaluation routine, in order to avoid that, in practice, the methodological evaluation continues to impact the ethical evaluation; 3) differentiation between the process of consent for participation on the research, and consent of its registration, expanding the form of registration to suit the various methodologies (art. 15 to 17) and the possibility of research without prior authorization process in cases justified in the system (art. 16); 4) clarification of research and of which preliminary steps does not need be evaluated (art. 1); 5) provision for the creation of an instance within CONEP for the implementation of the new CHS evaluation system, including a new registration form in Plataforma Brasil; 6) maintenance of the possibility of conducting covert research in justified cases (art. 14); and 7) departure from the reified notion of vulnerability and, consequently, adoption of a vulnerability criterion (art. 2, 3 and 20).

Luiz Fernando Dias Duarte, representing the CHS scientific associations at the GT-CHS, underscores the point at which the resolution could have advanced, but did not do it:

In a more localized way, it was not possible to find an adequate formula for the problem of FCA, monograph and similar works that involve direct research with social subjects; whose short period of realization can hardly be adapted to the centralized registration system, however agile it may become (art. 1, VIII). An oblique way out of the problem may be art. 27, with the registration of student projects as an amendment of a project registered in the name of the teacher or advisor. (DUARTE, 2016, p. 2).¹²

Also not contemplated is the reversal of the current situation of research with indigenous participants, considered high-risk by CONEP, a criterion that maintains a "tutelary view that is largely surpassed on the world scenario"¹³ (DUARTE, 2016, p.3). The progress of projects is dependent on the production of a specific resolution on the typification and grading of risks, which does not yet exist.

11- Tradução.

12- Tradução.

13- Tradução.

Guerrero (2016b) highlights the non-overcoming of a unique model of science, especially since art. 32 determines that anything not governed by resolution CNS 510/2016 will be governed by resolution CNS 466/2012.

It is clear that CONEP was unable to align all actors involved with research with human participants in the bioethical validation network. This would have been a unique moment to align the network in building a broad ethical perspective, grounded in a vision located in the social values shared intersubjectively by the actors and in a less dual paradigm in the relationship between biology and the humanities, but which resulted in dissent and controversy.

Ethics in social science research: controversies and debates

The discussion around a more plural ethical issue of research with human participants, as we have seen, has not been addressed in the CEP/CONEP System resolutions and forms, which portrays a legislative system partially detached from scientific practices and civil society discussions. While transparency, consent and risk are essential for biomedical research participants, on the other hand, the mechanisms for long-term monitoring research developments of the participants are restricted. With regard specifically to social sciences, the provocation that the participation of the GT-CHS in the discussion prior to the production of resolution CNS 510/2016 was not sufficient to cease the dominance of biomedical logic in research protocols and to introduce more pluralistic methodological parameters.

The conceptual discussion about the ethical dimension of scientific doing in the humanities is not taken into account and ethics is reduced to the principles of transposition of the ethical evaluation criteria and the risk typification criteria from the medical sciences to the humanities. It is assumed that standardization of procedures and forms is able to protect research participants, especially from the side risks of researchers' intervention. And this has a very traumatic origin in the history of medical research, as pointed out by Silva (2017). Research in the humanities and social sciences does not dispense with an ethical evaluation and can even become a reference in this sense, as it adds a pluralistic perception of science, having as its basis internal debates the dimensions of freedom and individual and collective autonomy, human rights, diversity, democracy, social vulnerabilities. The debate held by the GT-CHS with the CEP/CONEP System aimed to develop guidelines for addressing research ethics, taking into account the scientific work in the humanities and social sciences.

It is understood that resolution CNS 510/2016, the platform, committees and forms do not cover sufficiently the debate on research ethics, especially for research practice in the humanities. As Hüning (2017) points out, the treatment of research ethics primarily via protocols and bureaucratic instances paradoxically empties the broader ethical reflection of research.

For modern scientific rationality to know means above all to quantify. Scientific rigor is achieved with the rigor of measurements and, since it was not possible to quantify, any other production would be considered scientifically irrelevant (SANTOS, 2002). Social science researchers counter the imposition and view that science is experimentation, reproduction or hypothesis testing, arguing that what is produced using rigorous qualitative methods is also valid and reliable knowledge (DINIZ, 2013). In this sense, in order to address the differences in logic, the objective of the GT-CHS was to produce a different system from the CEP/CONEP System and external to the Ministry of Health.

The science war, as the attack on the scientific legitimacy of the humanities by science is commonly known in the United States, has mobilized and still mobilizes scientists around the supposed opposition between truth and reason on the one hand, and relativism and multiculturalism on the other. The charge of irrationality and obscurantism was used to disqualify the scientific making of a substantive part of the humanities. This discussion has intensified a hierarchical relationship between scientific knowledge that has existed since the advent of modern science.

This war, in a biological sciences *versus* humanities version, is expressed in the map of the regulation of research ethics in Brazil and divides scientists among those who believe in the existence of a unified and universal nature capable of solving and defining the common world and an opposite group that defends the impossibility of simplifying the historical process by which the common world is composed little by little (LATOUR, 2012).

The dimension of ethics in humanities research cannot be separated from the discussion of scientific doing. In the case of the modern social sciences it is a foundational debate, to which we can recall Max Weber's contribution. Weber defended the scientist's activity as in line with an interpretative and evaluative stance. It is not a question of undertaking a science capable of stating what should or should not be considered valid in terms of values, but of proposing a realistic science of morals, in which the values at stake in the conduct of individuals matter in order to understand and delimit the value of the subject its sphere of significant validity.

As Max Weber tells us, scientific work in the social sciences is based on "conceptual connections between problems" and not on "objective 'connections' between 'things'" (WEBER, 2006, p. 37) (Emphasis on the original). This position, the basis of interpretive theories, shifts the scientific work of the social sciences to another field whose objectivity has a different meaning from that proposed by the natural sciences.

It is a constitutive part of the social scientist's work the reflexivity about his own doing and its implications for the research subjects, considering that the social scientist has an empathic attitude towards the other in order to understand his social place and his social actions.

Given the peculiarities of research in the human and social sciences, it is not possible to separate the moral dimension from the ethics cultural dimension. The exercise of ethics is understood as being and existing in the world marked by emancipating moral and cultural principles that are beneficial to the collectivity and individuality. In this sense, there are some normative and evaluative principles of research in the humanities that need to be considered in an ethical discussion of the field:

Argumentative, relational and intersubjective logic

A substantive part of research in the humanities is qualitative, which implies the choice of comprehensive and intersubjective methods of investigation and analysis, in which the relationship between researcher and investigated group is a constitutive part of the production, truthfulness and legitimacy of the knowledge produced.

The humanities researcher investigates *in* and *with* his field, producing from this intervention new narratives, new arguments, related to a specific temporal space association of actors and agencies. If the bioethical dimension recognizes the need to replace the outmoded perspective of volunteer with the notion of participant, the need to think about participation and autonomy gains even more significant contours when it is assumed that much of the research results in the humanities were produced in the relationship of listening and joint action, for example in ethnographic studies, biographical studies, everyday life studies, participant observation, social cartography. In the practice of social sciences there is a state of tension between the known and the unknown (GOLDENBERG, 2011).

Anthropology is one of the areas most affected by ethical regulation, however, the relationship between ethics and anthropology is part of the tradition of anthropological thinking, as it recognizes and discusses the *interlocution* and *proximity* between researchers and participants in opposition to objectivity and distancing posture assumed in the conception of knowledge neutrality (SARTI; DUARTE, 2013). It is part of the ethical implications of anthropological making that, in general, anthropologists are in an unequal position in relation to research participants, both in terms of power and social legitimacy (SARTI; DUARTE, 2013).

Schuch (2013) identifies three spaces of ethical problematization in anthropology: the anthropologist's political performance, referring to the anthropologist's moral responsibility to the interlocutionary groups, especially in situations of conflict; multidisciplinarity, which refers to the debate between the particularities of anthropology as a science and the broader political and social demands that involve professional knowledge-producing scientists in collaboration with anthropology; and the field of regulation, which refers to the bureaucratic regulation and control movement of the ethical dimension.

By using as a parameter the traditional model of the natural sciences under which science has produced itself, the humanities set aside precisely what characterizes human actions: the intentions, meanings and their inherent purposes (ALVES-MAZZOTTI; GEWANDSZNAJDER, 2001). In this sense, the criticism that a form focused on research methodology, although not acknowledged in this way, leaves a relational dimension of ethics, which should be better explored in the postgraduate training of researchers, both in the humanities and in the field of natural sciences.

The research relation as a practice of listening and reworking the trajectory can produce intersubjective and subjective effects not initially foreseen, such as the denaturalization of certain objective conditions of the subjects. This facet is more intangible and sensitive than those for which it can be defined beforehand, as is the case with the distribution of economic benefits that may result from research.

If we consider, as Latour (2019), mistaken the separation between nature, characterized by being common and equal for all, and society, where difference and particularity lie, one could imagine the production of ethical protocols that meet the totality of scientific work with their hybrid collectives of culture and nature. Contrary to denying the ethical dimension to the humanities, this perspective understands that the ethical-scientific doing of the humanities can serve as an example for the natural sciences, since the dimension of biological nature is as hybrid and diverse as society.

Transparency, vulnerability and protection for participants

If knowledge is produced through a collective and intersubjective construction or a heterogeneous association of knowledge, both artificially anyway, what is meant by transparency? Transparency is a constitutive dimension of ethical rationality in democratic contexts.

There are data present since the beginning of the research, therefore, it is possible to think about communication strategies and mechanisms before, during and after the fieldwork, as Diniz (2008) warns us. Transparency is a process of building bonds, either in specific moments, such as in an interview, or in the long term, during daily and prolonged interaction between researchers and research participants. This is something different from a positivist perspective in which the *research subject* is active and interested agents and the *object investigated* are passive agents subordinate to the interests of researchers. In this sense, the commitment to transparency does not end in a form, but follows the process of knowledge production until the final stage of the return, when it is expected that some product is returned to participants. This feedback has stimulated debate about the dissemination or popularization of science in the humanities.

The protection of privacy in social science research introduces more complexity than can be identified from the resolution CNS 510/2016, in that, whether in a relationship of daily living as participant observation, or even in a subjective listening situation, such as the in-depth interview, the participants' memories and emotions are triggered. Deciding how to protect the privacy of the most intimate memories and emotions in the act of relating, the privacy of the participants, therefore requires permanent vigilance, an ethical exercise based on constant empathy and reflexivity.

The protection of research participants in the humanities is therefore built on the vulnerabilities peculiar to human relations. Risks such as exposure of privacy and embarrassing and humiliating situations, such as biographical situations, disruption of anonymity when it entails risks to the person, and risks linked to the context of the relationship, such as manipulation or abuse of trust, are some of the risks to be evaluated.

The tradition of social science research has been substantively built on the study of those who are marginalized, exploited, excluded and oppressed. Thus, it is urgent to deepen the debate on ethics in the scientific practice of these studies. One of the issues that is open in the current resolution is risk coding, which will impact studies with certain groups, either marginalized or state-sponsored. Such a dimension can only be seen on

a case-by-case basis within a logic of recognition of human rights, conceived more as a principle than as a code.

Transparency and protection for participants are not *a priori* irreconcilable positions between biomedical areas and the humanities, but the understanding of these terms varies with the science view taken. For biomedicine, protecting participants is primarily about guaranteeing their right to health and life, avoiding interventions and treatments that may cause present or future harm.

Humanities research mobilizes subject engagement beyond body and mind, mobilizing dimensions such as personal memories, beliefs and collective values. In this sense, the ethical dimension is understood here not in terms of moral codes, duties and commandments, but ethics as a dimension of the discernments constructed in the intersubjectivity of the social world, related to value orientation (HABERMAS, 2018).

Final considerations

Two strands stand out and are presented in the regulation of ethics in research with human participants and claim the scientific-social monopoly: one, dominant for a long time, understands that to study society it is necessary to apply, as much as possible, all the epistemological and methodological principles that dominate the study of nature; another, which claims for the social sciences its own epistemological and methodological status, based on the specificity of human being and his radical distinction from nature (SANTOS, 2002). The second variant claims for the social sciences its own methodological statute and puts the very idea of universal science under discussion.

The devices of *intéressement* mobilized by the National Health Council and CEP/ CONEP System were unable to align the collective of researchers from human and social sciences, which produced a field of tensions around the uniqueness of the ethical regulation norm in research with human participants, the risk typification model and the procedures for reviewing research projects. A relaxation in this position admits the need for recognition of methodological diversity, scientific pluralism and the production of public forums for debate on the ethics of the humanities, involving participants, researchers and civil society.

Regulation is just one of the dimensions of research ethics (SCHUCH, 2013). As Schuch (2013, p. 34) argues, in contrast to both the existence of a supposed universal ethic and an “adaptation of the general ethic to particular situations”, a performative dimension of the ethical stance is perceived.

If, on the one hand, we have demonstrated the particularities of research in the humanities, with particular emphasis on the theoretical-methodological tradition of the social sciences, on the other hand, we find the limits of this separation that ultimately reflects the separation between nature and culture. If we consider that scientific doing must be understood from situated discursive and material practices, then any science must depart from there to guide discernment and ethical precepts. Without disregarding the importance of protocols and regulations, we understand that ethics is expressed in scientific doing long before and beyond those.

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