

## Research ethics in the dynamic of scientific field: challenges in the building of guidelines for social sciences and humanities

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**Abstract** *The development of guidelines on research ethics for social science and humanities (SSH) takes place in the scientific field, marked by disputes aimed at the establishment of hegemonic scientific standard. In Brazil, the National Health Council is responsible for approving these guidelines, which involve certain specificities. Based on the authors' experience in the SSH Working Group of the National Commission on Research Ethics (GT CHS / CONEP), this article presents the process of development of guidelines for SSH, and some its challenges: the distance between the statutory guarantee and the effective execution of guidelines; the biomedical hegemony and the marginal position of the SSH in the CEP / CONEP system; the inadequacy of the current resolution facing the research features in CHS; the use of the concept of risk in guidelines aimed at SSH in the health area. Some interfaces and tensions in the debate between scientific merit and ethical evaluation are also discussed. The analysis highlights important impasses and difficulties regarding inter-paradigmatic dialogue in health research, considered the characteristics of the different traditions, the CONEP's heavily relying on the positivist perspective and the defense of that paradigm hegemony.*

**Key words** *Research ethics, Qualitative research, Epistemology, Public health, Collective health*

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## Introduction

Researchers from the social science and humanities (SSH) have pointed the inadequacy of guidelines on research ethics, inspired by biomedical sciences and improperly applied in other domains<sup>1,2</sup>. The consequences of this inadequacy are numerous and have been widely discussed without, however, having been resolved. A quick check to reference literature points to a wide production on the subject, both in Brazil<sup>1-11</sup> as in international literature<sup>12-21</sup>.

In Brazil, as a result of guidelines now in force, relevant research is delayed or even becomes unfeasible due to the delay or even refusal by the current system, formed by more than 600 Committees of Ethics in Research (CEP) and the National Research Ethics Commission (CONEP). Besides, what appears more severe, most of this research shows no ethical inadequacy to justify such retention. Such assertions are based not only on publications<sup>4,5</sup>, but especially in decades of academic life. Along the way, we have witnessing these and other problems, both in our personal experience and in the dialogue with key instances and groups, such as the Forum of Post-graduation Coordinators in Collective Health, groups and commissions at Brazilian Association of Collective Health (Abrasco) and other associations. Added to that, a continuous participation in various conferences whose topic was subject of debate, with countless testimonials and reports that support what we state here.

The still hegemonic positivist conception of science on the resolutions about ethics in research and the composition of CEP/CONEP system result in an adverse environment for SSH: inadequate resolutions are used as a reference for ethical review, most times, performed by groups unfamiliar with the analysis of projects operating outside the positivist paradigm. When referring to positivism, it is worth mentioning it, we do it in the broad sense of the term, which includes post-positivism and neo-positivism, since these paradigms are commensurable among themselves<sup>22</sup>. The hegemony of this paradigm over others in the health field, a phenomenon widely documented in the literature, results in losses to researchers from SSH, faced with the difficulty, sometimes crippling, to respond to questions that are valid for the positivist fit and do not fit in onto-epistemological terms to other approaches, such as the case of studies based on comprehensive or qualitative approaches.

In addition to the difficulties generated in the strict framework of the scientific field, where projects are refused and cease to be performed due to the problems mentioned, the society cannot enjoy the results of research that would be fundamental for understanding phenomena which involve complex social relationships, processes of meaning attribution and political issues beyond the mere description and measurement, among many other objects this approach deals with. The retraction effect operated in the production of knowledge is evident. To illustrate with an example already documented, after the beginning of work of the Canadian CEP, master's dissertations in sociology<sup>19</sup> and anthropology<sup>21</sup> changed the subjects studied, the generation and analysis of data and the methodology to adapt them to the demands of CEP. The interviews started to be used as the sole technique, and the number of participant observations reduced sharply.

Regarding the field in which we operate and serves as the basis of this discussion, the Collective Health (SC), depending on analysis focused on its epistemological configuration as knowledge production field, which is composed by certain disciplinary formations<sup>23</sup> or knowledge cores<sup>24</sup>: epidemiology; planning and health management; and human and social sciences, being this last framework the referential which operates an inaugural epistemological rupture to what today is conceived as SC, in contrast to traditional public health. The dynamics of this field illustrates in an emblematic manner the paradigmatic tensions alluded to in this explanation. More than that, it points to disturbing outcomes, especially if we glimpse the effective implementation and consolidation in the country of a health system guided by integrality, humanization, deployed in system quality, considered in its multidimensionality, intrinsic and extrinsic<sup>25</sup>, aspects that concern the SSH. Thus, how to disregard the specificities of SSH in health, in any of the praxis spheres, being the ethical review one of them?

### **The Construction of guidelines: recovering the context**

There were many years of struggle until the first Brazilian publication, prepared with the participation of national research associations in SSH, the report of the Municipal Health Department of São Paulo (2007)<sup>26</sup>, was sent to CONEP, stating the need for specific guidelines for SSH. Unfortunately, CONEP never manifested on this

proposal. Added to this initiative the approved motions at scientific meetings, in addition to manifestations of the following entities: National Association of Research and Post-Graduation Studies in Psychology (ANPEPP); National Network of Education and Research in Occupational Therapy (RENETO); Brazilian Association of Anthropology (ABA); National Association of Post-Graduation and Research in Social Sciences (ANPOCS); Brazilian Sociology Society (SBS) and the Brazilian Association of Political Science (ABCP) in the public consultation text that resulted in Resolution 466/12 of CNS<sup>27</sup>, acknowledging in his speech the need to a resolution specific to SSH:

*Ethical specificities of research in the social sciences and humanities and others that use specific methodologies of these areas will be covered in a supplementary resolution, given their particularities (XIII.3)*

June 2013 would mark an important time to construct the ethical revision system in Brazil due to two events: the publication of Resolution 466/12 and the first meeting SSH Forum, organized and composed by national associations of these knowledge areas. This Forum starts working along with the Ministry of Science, Technology and Innovation (MCTI) aimed at organizing a system of ethical revision, specific for research in SSH, both in terms of CEP structure and development of standards.

MCTI, it is worth remembering, at that moment, had a minister graduated in Social Science, was receptive to the proposal. However, subsequently, after being approached by a representative of the Ministry of Health, stepped back and decided that there was already a Brazilian instance with this mission, recommending that representatives of Forum SSH worked with the Health Ministry (MS). Simultaneously, it seems, after the dialogue between MCTI and MS, CONEP organizes a working group (WG) with the mission to draw up the resolution to SSH and invites representatives of the Forum and of other associations.

Not without reservations, especially with regard the intention of construction of a specific resolution out of CONEP/MS, various important associations of the SSH accepted the invitation, betting on a promising dialogue, naming and indicating representatives. The WG SSH is therefore set up within CONEP, composed of 18 national research associations of SSH, by CNS representatives and MS (Department of Science and

Technology (DECIT), of the Science, Technology and Strategic Inputs Secretariat (SCTIE). All researchers appointed by their respective associations are quite significant academically in their fields, many of them authors who published in important national and international journals on research ethics in SSH. It is therefore a qualified WG to fulfill the complex mission to develop a coherent resolution to the specificities the SSH, in its diversity, maintaining focus on protection of human rights of the research participants.

The first meeting of the WG was held in August 14, 2013 and from that date until July 2015, 23 meetings, as well the five joint meetings with the other CONEP's WG were accrued, which shows the intensity of effort this group and the magnitude of the challenge. The meetings took place in Brasilia, financed by DECIT/MS. This work resulted in a Minute<sup>28</sup> that, according to established deadlines, would be presented for public consultation in January 2015. However, this has not occurred so far (7 July 2015). On January 28, 2015, the WG SSH received a letter-answer<sup>29</sup> to the Minute, prepared by CONEP, generating unsolved impasses, although advances have taken place, and that, to our view, put the clash between the paradigms at the center of the ethical debate in progress, updating, in another sphere, the dispute between biomedicine and SSH.

In developing the draft, the WG SSH made an extensive study, based on a broad consultation to international documents on research ethics in SSH, prepared by different countries, among them Canada, which is worth mentioning because it is such a respectful and democratic referral of this situation. In 2008, at the time of the revision of Canadian guidelines, which resulted in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS-2)<sup>30</sup>, a working group was organized, composed by researchers from SSH, who drafted a specific chapter of TCPS-2. The TCPS -2 was prepared by the Secretariat on Responsible Conduct of Research and the Panel on Research Ethics, which considered the reports produced by various working groups, among which include: SSH; research with indigenous peoples; clinical research, among others. The introductory chapter of this document defines the principles to be observed in all research with humans, followed by specific chapters, each defining characteristics of research that address the ethical issues involved and the procedures. There is no relationship of subordination among the WG. Also, the TCPS-2 does not

subordinate one chapter to another. The definition of the TCPS-2 was made after two rounds of public consultation, carried out in Canada for two years. This process is so intense in Canada, that a new version was published in 2014.

In Brazil, the resolutions on research ethics have been elaborated in the framework of a main resolution and the others considered complementary, focused on specific topics. In this logic, the resolution for SSH, now in preparation, would be complementary to Resolution 466. In practice, this means that the ethical review of research on SSH, conducted by the CEP/CONEP system should be based on these two resolutions. To prevent this from happening, since the positivist paradigm is impregnated in 466, the WG SSH considered necessary to ensure that the resolution SSH did not omit at any point of 466. This resulted in a long Minute<sup>28</sup> as an alternative to drawing up a resolution which focused on ethical principles and not on the procedures arising from them. The more detailed the Minute, the greater the difficulty of the SSH, in its paradigmatic and theoretical and methodological diversity, to reach a consensus.

Preparing this text, we see the regrettable lack of publicity of this work, which should be published on the CONEP site. This commission would need to transpire the existence of WG, its composition, the Minute, the CONEP letter, among others, to allow social control of this work. The absence of such disclosure motivated us to build this text in order to present this information, with the reservation that there is no claim to represent the WG or speak in its behalf here.

Recovered these contextual aspects, indispensable to understand the way in which this reflection is recorded and the crucial moment in which this construction is placed in Brazil, in this article we present some elements which sound very strategic in the process, considered, as the title anticipates, in the dynamic of the scientific field. Given the text boundaries, we elected focal points, clarifying that great part of them is inspired by the criticisms of the Minute built by WG<sup>28</sup> in the document prepared by CONEP<sup>29</sup>. This option seems to us timely, not only due to the relevance of its content, but because this document records the official discourse of CONEP. Beyond a dispute between groups, or instances, this document illustrates in an emblematic form the difficult and strained dialogue between the biomedical paradigms (Positivist) and SSH already alluded

to before. We will focus, in the sequence, on the distance between the guarantee on the legal plan and the execution of guidelines; the biomedical hegemony and the marginal position of SSH in the system CEP/CONEP; the inadequacy of current resolution before the research characteristics in SSH; the issue of employment of the concept risk in guidelines aimed at SSH in the health field, as well as interfaces and tensions in the debate between scientific merit and ethical review.

### Guidelines: in law and in fact?

We will start by pointing out that reaching a Minute, intending to legitimize it as a resolution, indicates an important route, but not sufficient for a transformation process. Here, we need to recover the classic statement of Bobbio<sup>31</sup> *as for being [...] practical function of language of rights, one to lend particular strength to demands [...] while it makes it misleading and obscures the difference between the claimed right and recognized and protected right*. They are all too familiar, especially for those working in areas such as education and health in Brazil, the challenges facing the realization in practice of the achievements set out in the legal sphere. Ensure in terms of Resolution already means a lot regarding ethics guidelines specific for SSH, but that is not all, taking as an example our Constitution. The Brazilian Constitution is one of the most advanced in the world, in particular concerning the rights in the health field, but there is still a considerable distance between the speech and the realization of what is “guaranteed”.

Moving from these premises to the specific ethical guidelines for SSH, it is evident the need to, in addition to trigger a new discourse, launch a process that leads to the execution of such guidelines. This process encompasses two fundamental aspects: a first one, concerning the construction of a new culture within, not only CONEP, but the hundreds of Brazilian CEP and in the academic community; the second aspect, intrinsically associated with the first one, refers to a communicative action in several other plans as crucial mechanism in that case. It is evident, therefore, the need for the maintenance of a working group, well qualified, as a fundamental leadership in the paradigmatic change required to pass from theory to action in the daily ethical assessments under the aegis of specific guidelines to the different approaches of research and science visions.

For this achievement to take place it is key the micro space represented by daily relations, as those established inside committees; between them and the institutions of research, besides developed relationships between several other instances. The everyday while space of living experience is the place where social actors construct their perceptions, at same time it represents a space for fight, for exercising power, power here understood as a social practice and as such constituted historically; and we can distinguish in it one macro level and another one micro of exercise<sup>32</sup>, both active in this process.

It would be naive to assume that the materialization of specific guidelines for certain members of one community would escape to the dynamics of power, especially that characteristic of a strongly autonomous field as the scientific field. In this regard, it is useful to return once more, to the lucid formulation by Bourdieu<sup>33</sup>, stating the inseparability between science and politics. The route for the construction of guidelines, still inside CONEP, has already identified, at various times, apparently epistemological clashes, but covering different political views for the knowledge building process and other interests, making it clear that new clashes will come. I was just thinking the guidelines as a living process that Minute<sup>28</sup> of SSH WG incorporated in Article 35 the composition of a WG aiming to ensure the continuity of process has already started:

*CONEP, after the approval of this Resolution, will create a Working Group on Ethics in Research in Social Sciences and Humanities, with the participation of its members from Social Sciences and Humanities, and representatives of national scientific associations in Social Sciences and Humanities, , members of CEP that review research ethics in SSH and users [representatives of community], for the implementation, monitoring and updating of the guidelines established in this Resolution, as well as training proposals in the area.*

Without this, it will become difficult to implement of the advances aimed at by the effort of SSH WG/CONEP. An analysis of the composition of the system CEP / CONEP will make clear what we state here.

#### **CEP/CONEP System and biomedical hegemony**

To analyze the composition of CONEP, we resort to the National Council configuration for Scientific and Technological Development

(CNPq)<sup>34</sup>, composed of several Research Coordination Groups, among them two of particular interest to the theme discussed here: the Coordination of Research Program in Humanities and Social Sciences- COCHS and Coordination of the Research Program in Social Sciences and Education - COSAE. Based on this classification prepared by CNPq, and with no intention to ratify it or even question it, therefore taking it only as a source, we identified 26 subjects included under the broad name Humanities and Social Sciences, and Applied Social Sciences and Education. A national commission, as the CONEP, which aims to develop guidelines on research ethics for research involving human beings, directed to all areas of knowledge, including for external research to the health field, which would be their legal authority, assumes a composition of great amplitude, if suitable for this purpose. This is not what is observed when analyzing the composition of CONEP, based on official information presented in this Commission<sup>35</sup> site. From the current 30 full members of CONEP, 8 are CNS indications, 4 are users representatives, 2 are employees representatives and 2 are appointed by the Science and Technology Department (Decit/SCTIE/MS), as established by the Resolution 446/11<sup>36</sup>.

Among the 22 who were selected from referrals made by CEP, 18 are professionals with a degree in biomedicine, biological sciences and health sciences and only 4 members have a degree in the Humanities, Social Sciences and Applied Social Sciences. Of the five deputies, four are from the biomedical area. Facing this scenario, we are concerned about the dissonance of the expected expertise to achieve a task of this magnitude, and the following question emerges: what is the legitimacy (in epistemological terms) of a collegiate composed in such manner to decide on a resolution to SSH? More than that, to veto – according to the response letter from CONEP the proposal prepared by SSH WG, considering their expertise? What to expect with regard to comprehension and effectuation of the guidelines resulting from the arduous challenge that now arises, and fruitful work done by the aforementioned WG? The data speaks for itself and show, given the not guaranteed necessary diversity and even interdisciplinary critical mass demanded in order to deal with that task.

The CONEP<sup>29</sup> letter shows a lack of knowledge even about what the field of Social, Human and Applied Social Sciences is, using the CNPq terminology. On page 7 of that document is:

However, it would not be prudent to stimulate the composition of Ethics Research Committees without the necessary and salutary multidisciplinary vision. As a reminder, the CNS Standard Operating Rule Number 001/2013 defines in item 2.2, that CEP [...] may vary in their composition, according to the specifics of the institution and research topics to be analyzed. There will always be a multidisciplinary character and there must not be more than half of its members belonging to the same professional category; including people of both sexes. It may also rely on consultants “ad hoc”, belonging or not to the institution, with the purpose of providing technical inputs.

It is understood, therefore, that the multidisciplinary aspect of the Research Ethics Committees is *conditio sine qua non*. (Emphasis as original). This excerpt highlights the belief that all the disciplines that compose the wide range of human, social and applied social sciences constitute a single discipline. It is widely known (or should be so in dealing with regulatory instances of research) that the SSH have as a signature the paradigmatic diversity, which in terms of analytical lines, makes the literature refer to a “Babel”<sup>37</sup> effect given the internal diversity. This can not be equalized to the biomedical “specialties” in isonomic relationship, since such specialties, on the one hand, are distinguished by objects dealt with, on the other, are unified for adhering to the positivist screening in which all specialties rest, unifying them epistemologically in what we conceive as a model or biomedical paradigm.

The CONEP letter seems to consider that a CEP composed of representatives of different domains (subfields) of SSH would not be multidisciplinary, even if it included historians, philosophers, psychologists, sociologists, anthropologists, social workers, teachers etc. Such ignorance expressed in distinct impacts distinct spheres, revealing tensions between the two instances: CONEP and SSH WG. Let’s look at some.

CONEP expresses, in this document, contrary to its composition being gradually equivalent in numbers between biomedical sciences and human, social and applied social sciences, as observed in the excerpt below:

[...] it seems incoherent to propose that 50% of CONEP members are from the CHS area, when there is expectation that most studies in this area do not fit into what in the future will be called “high risk research” [...]. It was considered, therefore, that the articles 34 and 35 of the Minutes of the SSH WG resolution are incongruent with the CEP/CO-

NEP system. However, these articles are imperative for a CEP/CONEP system, which can identify and, more than that, respect different research traditions and ethical aspects involved in each one. CONEP’s posture in this document preserves the already alluded biomedical hegemony, positivist, over other kinds of research.

An equal representation at CONEP is important because it’s up to it, as a regulatory instance, to prepare and update the resolutions on research ethics and not, as we read in the CONEP letter, to assess research protocols, which would be linked to a number of quantitative reasoning protocols of this or that area/field. The proposal of an equally composed CONEP has the purpose, precisely, that decisions on ethics guidelines to be followed in the country are made by a group of researchers who work on different paradigms. However, it is a huge challenge to ensure this diversity. Due to the lack of a better option, the Minutes proposes that CONEP have equal representation between biomedical Sciences and SSH. Knowing in advance that there are researchers in SSH working on the positivist paradigm, and that among the biomedical there are those who work in other paradigms. However, we understand that it would not be operational to write in the minutes that the composition of CONEP should be equal, between positivist researchers and researchers working in critical, constructivist and participatory paradigms.

Notwithstanding the refusal to parity expressed in the letter response to the Minute, it should be noted that today, in view of the strong resistance of the SSH WG and the mobilization effected by it within the collective they represent, unfolded into a dialogue counting on the mediation of the CNS direction, to which the WG also reported, CONEP coordination already signals to the progressive equity, to be achieved up to 2017, starting by the indications that will take place later this year.

This is an important advance since the biomedical majority composition of CONEP, if maintained, would prevent researchers representatives of the SSH from taking positions that would allow them to effectively participate in the construction of a CEP/CONEP system, congruent with the specificities of different disciplines that compose it. A brief recapture of Resolution 466/12 can help view the challenges that now arise for an effective dialogue between biomedicine and the SSH.

### The inadequacy of Resolution 466/12 for Social Sciences and Humanities

It is worth quoting some excerpts that illustrate the inadequacy of Resolution 466/12 for SSH. For example, the item III.2, which deals with ethical issues of research in any field of knowledge, and includes the following sub-items:

r) *take into account, in research conducted on women of childbearing age or pregnant women, assessment of risks and benefits and possible interference with fertility, pregnancy, the embryo or fetus, labor, the puerperium, nursing and the newborn;*

s) *consider that research on pregnant women must be preceded by research on not pregnant women, except when pregnancy is the essential goal of the research;*

t) *ensure to women who expressly declare exempt from pregnancy risk for not exercising sexual practices or for exercising them in a non-reproductive manner, the right to participate in research without the compulsory use of contraceptives.*

The inadequacy of these items for the research on SSH is so evident that it makes any explanation or comment unnecessary. If applied, to respect this item, the assessments of health services should be carried out only with non-pregnant women, and only then include the pregnant ones. That makes no sense. How to guide the assessments with a resolution that, all the time, impose restrictions, exceptions, other criteria?

However, there are finer points which show the foundation of the 466 based on the positivist concept of science. The X item deals with procedures for ethical analysis and item X.3.2 states: *CEP and CONEP may have consultants ad hoc, people belonging or not to the institution/organization with the purpose of providing technical subsidies.* This wording is a step backwards from the res. 196/96<sup>38</sup>, where the VIII.2 item, which deals with the composition of CONEP, reads: *You can also count on consultants and ad hoc members, assured the representation of users.* This passage of 196 provided for the possibility that an ad hoc could one speaking from the standpoint of research participant and not necessarily from a technical point of view. Resuming Santos<sup>39</sup>, when discussing the dual epistemological break, stating that after the first break that distanced science from common sense, the current challenge would be to expect scientific knowledge to transform itself into *a new common sense, a common sense better informed*<sup>39</sup>.

As seen in the passage quoted from 466, the research participant's view is excluded. More than a positivist conception of science, which opposed to common sense, a contradiction is evidenced: a resolution that aims to the protection of the research participants ends up disqualifying their knowledge. This is just one example of an impregnated worldview throughout the text of Resolution 466/12, not being possible to take it by operating only partial changes. Therefore, the SSH WG rightly included Article 33 which states that only the items dealing with the CEP/CONEP system will be valid for SSH.

Finally, we would like to, at least, mention the evaluation of scientific merit and ethical review, sometimes object of misunderstandings and often considered as independent aspects. Now, even considering the issue only in the restricted SSH scope, a researcher in this area that works on a theoretical and methodological framework may find it difficult to properly assess the scientific merit of a SSH project guided by another referential. Nonetheless, it is evident the need for the CEP/CONEP system to keep its concern to ensure the scientific merit of the projects, once a project that does not hold this merit is not ethically appropriate; however, this should be done by requirement of proof that such an assessment was made by existing competent instances in the country, whether, qualification boards; research commissions; funding agencies and other properly qualified procedures. The scientific merit evaluation, done improperly, does not correctly identify the ethical implications of research. Also, it is good to remember, this has been one of the main complaints of SSH researchers in these almost 20 operation years of the CEP/CONEP system.

### The challenge in the dialogue with biomedicine about risk rating

Another key point in the discussion on research ethics guidelines, refers to the definition of "risks" or risk level, again, object of dissent between SSH and biomedicine.

Throughout the intense process of construction of a specific resolution under the burden of SSH WG, at various times discomforts were felt, not only regarding the definition of the so-called "risk levels", at one point, but also in relation to the employment of the term/concept "risk". As discussed in one of the WG meetings, by one of the authors of this manuscript and object developed in another article in this journal<sup>40</sup>, risk takes,

in SC, peculiar meanings, being problematic, and in some cases, incongruous in this process, precisely, given the irreconcilable distinctions between the modalities of biomedical research and SSH research on health. In the health field, especially in collective health, the preponderance of the idea of calculus and probability, therefore predictability, is reiterated in a vast bibliography. Therefore, building a “Risk classification” that meets the both areas codes in an attempt of a “pairing” becomes a very complex task.

Also, despite statements towards a multi or interdisciplinary scope, many difficulties of dialogue between the hard and soft cultures, especially for researchers developing SSH research in health, especially in the qualitative approach are revealed. Not coincidentally, in one of the meetings, an effective distance of the concept of risk was held within these guidelines. The use of the concept of risk deployed in dialogues with actors coming from the health sector, despite the qualitative and quantitative meanings present in social theories, triggers the mathematical-probabilistic reasoning, hegemonic in this area, even when concerning situations when uncertainty and unpredictability are inherent, as in SSH research.

Such argument, although accepted in its bases by the WG, did not get enough force to block its employment and replace it with another concept which, safeguarding its meaning, did not carry the semantic difficulty already pointed. It was assessed that keeping the concept in the text would be more favorable to dialogue, but, considering what would occur, we question whether such maintenance effectively contributed to overcome the difficulties or if it accentuated them by admitting a conflicting understanding with the epistemological soil in which the guidelines proposed are founded. Once WG has always had clear the existence of difficulties to understand about differences between procedures of biomedical sciences and the SSH, another outcome would not be expected other than the repetition of certain quantitative positivist sense, in building risk gradation and related procedures. The re-established dialogue process between SSH WG and CONEP, already described, had also positive results in this respect: a resolution on risk classification and processing on the system CEP/CONEP will be prepared, containing two chapters, being one specific to SSH.

## Final considerations

One of the criticisms that the resolution minutes received during the National Committees Meeting of Ethics Research (Encep), held in November 2014, was that it would be contrary to transdisciplinary. It questioned whether the existence of a resolution to SSH and CEP targeting these areas could lead to distance of the disciplines. However, it is crucial to register that a transdisciplinary scope breaks walls between the different disciplines and articulates different knowledge and concepts for the comprehension of complex objects. There is no hierarchical relationship between disciplines, which started to articulate and build the object of study during the research process<sup>41</sup>. Here we touch another argument of the CONEP letter which states that *the researcher must develop the project as outlined [...]*. If we are under the trans-disciplinary view, how to outline the project previously if the object itself moves and is being built along the process?

Nonetheless, as the CONEP letter points out, the search of this commission is for a multi-disciplinary character, therefore far from the transdisciplinary proposal. Through the practice of CEP/CONEP system and the composition of CONEP, one can identify, in fact, the model of auxiliary inter-disciplinary approach<sup>42</sup>, in which different disciplines would be integrated by a hierarchically superior disciplinary field, in this case, the biomedical one. It is, therefore, a proposal very far from the trans-disciplinary approach. What seems to happen between the CEP/CONEP system and the SSH WG is the predictable impossibility of inter-paradigmatic dialogue, to which is added a “colonizing” posture, determined by the positivist scrutiny, considered as the only legitimate, and which intends to submit researchers from SSH to its parameters.

Also, when it demands the use of the concept of risk in a different meaning of that

congruent with the fundamentals of SSH, and further, that a single classification of risk is prepared for SSH and Biomedical areas.

It is important that a GT CHS/CONEP (SSH WG/CONEP) continues working after the approval of the SSH resolution, establishing mandate for its members, and taking the leadership of the process for a paradigmatic shift, needed to pass from paper to action in routine of ethical reviews under the aegis of specific guidelines. This progress depends on an effective dialogue, which implies the establishment of non-hierarchical relationships, in listening to the diversity, respect



to otherness and not in the posture that seeks to impose to what is different, divergent and instituting in the contrast with their own worldview.

## Collaborations

ICZ Guerriero and MLM Bossi participated equally in all stages of preparation of the article.

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