

# Controversies on the ethical review of research in the Humanities and Social Sciences by System CEP/Conep

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## Abstract

The Ethics Committee must review all researches involving human subjects conducted in Brazil, which has caused controversies about the ethical review of research in the humanities and social sciences. The purpose of this article is to discuss the controversies of the ethical review of research in these areas in System CEP/Conep. The controversies are the biocentrism, the punctual improvements in Resolution 466/2012, the emergence of a parallel system of ethical review for these areas or the constitution of supplementary resolution in the system CEP/Conep. These controversies relate to functional limitations of the ethical committees: high demand of projects, few committees, limitations of the Brazil platform and the need for members training. The System CEP/Conep should continue as the only system of ethical review in Brazilian research; but it requires that the resolutions are continually revised in order to include the specificities of the researches in the humanities and create more committees with better training.

**Keywords:** Ethics committees, research. Ethics committees. Ethical review. Ethics, research. Science. Humanities. Social Sciences.

## Resumo

### Controvérsias sobre a revisão ética de pesquisas em ciências humanas e sociais pelo Sistema CEP/Conep

O comitê de ética em pesquisa tem como função revisar todas as pesquisas envolvendo seres humanos realizadas no Brasil, o que tem suscitado controvérsias sobre a revisão ética de pesquisas em ciências humanas e sociais. O objetivo deste artigo é discutir as controvérsias da revisão ética de pesquisas dessas áreas no Sistema CEP/Conep. São controvérsias o biocentrismo, as melhorias pontuais da Resolução 466/2012, a emergência de um sistema paralelo de revisão ética para essas áreas ou a constituição de resolução complementar própria no Sistema CEP/Conep. Tais controvérsias relacionam-se com limitações funcionais dos comitês de ética: grande demanda de projetos, poucos comitês, limitações da Plataforma Brasil e necessidade de capacitação dos membros. O Sistema CEP/Conep deve continuar como único sistema de revisão ética em pesquisa brasileiro; mas necessita que as resoluções sejam continuamente revisadas para contemplar as especificidades das pesquisas das áreas humanas e que sejam criados mais comitês com melhor capacitação.

**Palavras-chave:** Comitês de ética em pesquisa. Comissão de ética. Revisão ética. Ética em pesquisa. Ciência. Ciências humanas. Ciências sociais.

## Resumen

### Controversias sobre la revisión ética de la investigación en ciencias humanas y sociales por el Sistema CEP/Conep

El Comité de Ética en Investigación debe revisar todas las investigaciones en seres humanos realizadas en Brasil, lo que ha causado controversias acerca de la revisión ética de la investigación en ciencias humanas y sociales. El propósito de este artículo es discutir las controversias de la revisión ética de la investigación en estas áreas en el Sistema CEP/Conep. Las controversias son el biocentrismo, las mejoras puntuales en la resolución 466/2012, la aparición de un sistema paralelo de revisión ética para estas áreas o la constitución de una resolución complementaria propia en el sistema CEP/Conep. Estas controversias se refieren a las limitaciones funcionales de los Comités de Ética: gran demanda de proyectos, pocos comités, limitaciones de la plataforma Brasil y la necesidad de capacitación de los miembros. El sistema CEP/Conep debe continuar como único sistema de revisión ética en investigación brasileña; pero requiere que las resoluciones sean revisadas continuamente para contemplar las especificidades de las investigaciones en las ciencias humanas y ciencias sociales y que sean creados más comités con mejor formación de los participantes.

**Palabras-clave:** Comités de ética en investigación. Comités de ética. Revisión ética. Ética en investigación. Ciencia. Ciencias Humanas. Ciencias Sociales.

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Declararam não haver conflito de interesse.

The study object of this article are the controversies over the ethics review of researches in the humanities and social sciences by CEP/Conep System, since all research involving human beings, regardless of the scientific knowledge area, must be ethically reviewed by the research ethics committee (CEP).

The relationship between science, technology and ethics deserves special attention with regard to social control in research, considering this control to be connected to the fundamentals of science and technology policy developed in Brazil, since research has great importance for the social, scientific and economic development of a country, contributing to social improvement, educational, health and living conditions of the population. This means that the scientific work developed in contexts whose cultural determinants are in constant and rapid construction, presenting challenges to the understanding of the scientist's role in society, the reality in which his research is comprehended, and the implementation of social control of researches in various areas of knowledge.

The realization that scientists are human beings, whose ethical behavior is a dynamic and evolving construct, and the existence of several areas of scientific knowledge, with multiple ways of designing and doing research, indicate the challenges that the CEP/Conep System must face to establish social control in research that takes into account the specificities of all these areas of knowledge, in order to increase its effectiveness, since CEP are made increasingly necessary and present in the construction of the relationship between ethics, science and technology.

In this context, it is important to remember that the National System of Ethical Review of Research Involving Humans, better known as CEP/Conep System, was created by the Resolution 196/1996<sup>1</sup> and is formed by a national body, the National Commission for Ethics in Research (Conep) and by the CEP. Substitute of Resolution 1/1988<sup>2</sup>, focused only on researches in health and no significant practical results, Resolution 196/1996 was elaborated by an Executive Working Group (EWG) after a long process of public consultation, and was intended, among other things, to regulate research activities involving human subjects conducted in various areas of scientific knowledge in the country<sup>1</sup>.

Despite its practical application, the Resolution 196/1996 required revision, in order to follow the changes in the scientific world and the very CEP/Conep System, as well as to make broader the concept of research and to meet the specific needs

of non-biomedical research, in order to settle controversies generated by the conduct of research in these areas in the system. Thus, in 2011, a public consultation was carried out so that the whole society could contribute with suggestions for the revision of the resolution. The material collected in this consultation was analyzed by a working group and the conclusions presented in 2012 at the 1<sup>st</sup> Meeting of the Special Research Ethics Committees, held in São Paulo<sup>3</sup>. As a result of this effort, the Resolution 466/2012<sup>4</sup> was approved by the National Health Council, which maintained the organizational structure of the CEP/Conep System and brought specific advances to the system, including the prediction of the elaboration of complementary resolution for research in the humanities and social sciences.

National body of the CEP/Conep system, linked to CNS, the National Commission for Ethics in Research is a joint committee of advisory, deliberative, educational and independent nature, whose composition, multi and interdisciplinary, consists of 30 members and 8 surrogates of both sexes. Among its functions are distinguished: stimulating the creation of ethical review committees; approval and monitoring of research projects of special areas (that do not have specific legislation and/or require the assessment of Conep to be developed); development and dissemination of specific standards in ethics; formation of an information system for the provision and monitoring of ethical aspects of research involving human subjects<sup>1,3-6</sup>.

The CEP are collegiate regional bodies, interdisciplinary, interdependent, of public munus, which integrate the mechanisms of social control organized in order to seek humane treatment to research participants. Also, they have as mission to safeguard the rights and the dignity of participants, so that their interests are considered above the interests of science and society, especially the most powerful social groups. Its functions include, among others: the review of research protocols involving human subjects; opinion issued, embodied of the approved research projects; performance as advisory and educational role; receiving complaints of violation of ethical aspects by researches involving human subjects; the continuous communication with Conep<sup>1,4,7</sup>.

The first attempt to computerize the CEP/Conep System was the National Information System for Research Ethics (SISNEP), which was a means of internet communication on information required by CEP, researchers, Conep and the general population. The SISNEP was created, among other purposes, to:

*facilitate the registration of research involving human subjects and to guide the course of each project [...]; to include the ethical evaluation system in research in Brazil (CEPs and Conep) [...]; to expedite the handling and to facilitate researchers to monitor the status of their projects [...]; to allow monitoring of projects already approved [...]* <sup>8</sup>. However, this system was limited to whether the cover pages of research projects involving human subjects, and to the information of the final outcome of the ethics review of projects, and never came to include all active CEPs in the CEP/Conep System.

In 2012, the SISNEP was replaced by Brazil Platform, an online system for reviewing the ethics of research projects involving human subjects that records the whole process of work of CEP/Conep system through public modules, CEP, Conep and researcher. In this system, it is possible for researchers fill in the details of the projects, to enter all relevant documentation, to submit the project to the CEP, to track its progress in the system, to receive the opinion embodied right after the meeting, to respond to pending issues in projects, to start the monitoring process of approved projects and to submit reports. The CEP and Conep it is expected to forward projects to reviewers, to review the projects, to write opinions, to insert the agenda and hold meetings, to prepare minutes of meetings, to analyze the answers to the outstanding issues, to review notifications and amendments (monitoring of approved projects), to send embodied advice to those researchers and to analyze and advise on the reports submitted by researchers. Also, on its home page, the project numbers submitted to the CEP and Conep are available for public consultation.

In this context, considering that the CEP/Conep System must appreciate all research involving human subjects conducted in Brazil, the multiplicity of disciplines and interdisciplinary (understood as an effort to correlate disciplines <sup>9</sup>) of knowledge involved in researches are challenges to the conformation of ethical criteria of the CEP/Conep system as responsible for social control of researches involving human subjects. These challenges present us with a field of study of social relevance, in which how the system institutionalizes the ethical practice in researches is susceptible to changes facilitating dialogue between the CEP and researchers. This is due to the various methods and theories used in research in various areas of scientific knowledge, making important therefore the discussion of controversies about the ethics review of research in the humanities and social sciences under the CEP/Conep System.

Thus, this work has as guiding question: what are the controversies over the ethics review of researches in the humanities and social sciences in the CEP/Conep System? To answer this question, we developed the following objective: to discuss the controversies about the ethics review of research in the humanities and social sciences in the CEP/Conep System, in order to show their challenges and possible alternatives to the more comprehensive construction of the dynamic techno-ethical- scientist, considering how the CEP institutionalize theoretical and conceptual delimitation of making ethical in research developed in Brazil.

## Methods

This update article emerged from discussions on the ethical review of research in the humanities and social sciences in the context of the discipline Introduction to Science and Technology Policy, the Graduate Program in Science and Technology Policy at the State University of Campinas (PPG-PCT / Unicamp). To support our discussion, ten articles were selected from the researches performed on Google Scholar databases, and SciELO Portal Capes, between the months of May and July 2014, using as keywords the following terms: “the Ethics Committee search”; “Committee on Ethics in Research in the Humanities”; “Supplementary resolution to the Humanities”; “Ethical review”; “Ethical review in research and specific system of ethical review for the Humanities”. We also use books, a dissertation, a doctoral thesis, the parent resolutions System CEP/Conep (the repealed Resolution 196/1996 and its replacement, the Resolution 466/2012) and other resolutions that were relevant to the study. In addition, we visited the sites of Conep, the Ministry of Education (MEC), the Brazilian Anthropological Association (ABA) and the Committee of Ethics in Research in Social Sciences of the University of Brasilia (CEP / IH / UNB).

## Controversies in ethics review of research in the humanities and social sciences

### *Process of ethical review of research*

Unlike the exact and biomedical sciences, which tend to establish itself in alleged neutrality, announced in the relations between subject and object, the methods and empirical procedures of the human and social sciences are seen as inherently

ethical, since they are made from and through establishing relationships with other human beings. The social scientist is continually building perspectives between identification and distance, between senses and recognition, relationships on which the postulated neutrality may not be desired in its simplest sense. As Rabinow<sup>10</sup> would say, its main thread is ethical for not referring itself to a code external to the research, but for explaining the complex condition in which the researcher finds himself to: interdependency with the researched and the complex reality of which both participate. In other words, research in the humanities is characterized by the construction of these complex spaces, spaces *in between*<sup>10</sup> that exposes its ethical bias. It is in these terms that the participation of social scientists in ethics committees in research and the development of the own code of ethics must be considered.

From this it follows that the revision of Resolution 196/1996 and its transformation into Resolution 466/2012 became more apparent the controversies over the ethics review of research in the humanities and social sciences by CEP/Conep System. The process unveiled the system limits on the specificities of non-biomedical areas and the need to change how the ethical relationship between areas of knowledge is established, in the institutional and formal dimensions in the dynamics of CEP. Hence, we try to fit more and more the activity of CEP, as these committees represent a contingent way to respond to ethical issues raised by scientific research as ethical practice. According to De La Fare, Machado and Carvalho<sup>11</sup>, there is a certain critical consensus on the resolutions 196/1996 and 466/2012, such as biocentrism, normative formalization (which paralyzes research in humanities and social sciences), prescribed protocols, and strict and compulsory application of the Informed Consent (IC). These criticisms may be exemplified by the ethical review of research projects in the humanities and social sciences with the use of methodological parameters from the biomedical areas and by the IC request in situations where it is not feasible, such as in researches involving offenders or in the study of practices considered illegal under Brazilian law, such as abortion.

Therefore, it is important to consider that in resolutions 196/1996 and 466/2012, the controversies are also expressed in the use of the term "research involving human beings, giving that, according to Oliveira<sup>12</sup>, the term encompasses surveys *with* and *in* humans. The difference between one and another is that research *with* humans requires dialogue between researcher and researched, while

research *in* humans involves bodily intervention, that is, consists of drug or equipment testing and is therefore invasive. However, Port<sup>13</sup> alerts to the fact that any type of research involves at least one human being, including those carried out on animals or the ones that has no living being as subject of the research (such as library researches), since the researcher that accomplishes *is* human. In addition, the author also recalls the case where the surveys can not be classified neither as research *with* humans or as research *in* human subjects, as the genetic research that can be made from organic material gathering, as cells skin, hair or nail chips, a fact that points to the importance of considering the term "involving" human beings in the classification of studies and their implications on the definition of ethical strategies to be adopted to protect the participants, whether individuals or communities.

Hence it infers that the controversies raised by the ethical review of research projects in various areas of knowledge in the CEP/Conep System bring to the fore different ways of conceiving scientific research and its realization as an ethical activity, highlighting the growing need to ensure participants observing canons as integrity, beneficence, non-maleficence, autonomy, among others. This means that the need to conduct ethically responsible researches, although implicitly permeates the discussion, must be emphasized and strengthened and that CEP, by making the ethical review of research projects, contributes to research involving humans to achieve high ethical standard .

This ethical review undertaken by CEP comprises the research project as a whole, focusing on the objectives, methodology, data collection instruments and the Terms of Informed Consent (IC) in order to protect the research participants, considering the close relationship between these constituent items of the project and the research in ethics, since, according to Diniz and Sugai, *research techniques are important for ethics review because unveil how researchers plan to recruit participants, how the participation will be defined and, in the case of studies with risk beyond the minimum, if the benefits justify effects or damage to the interests of the subjects*<sup>14</sup>. From this it follows that the ethical review of CEP contributes to the ethical-scientific improvement of the analyzed projects, as well as for its development in ethically accepted standards.

As for the researches in human and social sciences, it is important to note that although there are differences in its operation, the scientific method used has much merit as that used in the exact

and biomedical sciences, with the exception that projects in humanities and social areas have technical characteristics and can sometimes require more sensitivity of the referee and the CEP for their analysis. This is because the resolutions that guide the CEP/Conep System are focused on biomedical researches, here understood as those that are located in special areas of Groups I and II, and of the knowledge areas classified in Group III of the title page for research involving human subjects, from Conep. However, remember that this classification does not exhaust nor limits the possibilities of research in biomedical and not biomedical areas.

According to Diniz<sup>15</sup>, the sensitivity of CEP to deal with different ways of doing research does not mean complicity with researchers, but denotes that the challenge of ethical review in the humanities and social sciences comprehends the identification of the ethical implications present in the methodological option of each project, without inquiring about the status of reliability of research techniques to be employed by the researcher.

#### *Functional limitations from CEP/Conep System*

Another aspect that influences the controversies of the ethical review of research projects is the large amount of projects in review process by CEP, a fact that, in our view, causes bottlenecks as work overload to referees and the delay in the assessment of many projects under the CEP/Conep System, possibly leading to a loss of funding and/or commitment of time to the development of many projects submitted to CEP, whether from the humanities and social sciences or others<sup>16-18</sup>. Hence it infers that, despite having about 684 registered CEP<sup>19</sup>, the system still does not account to meet the 2,653 higher education institutions in the country<sup>20</sup>, since, in addition to the demand for the assessment of graduation research projects, the committees have yet to analyze the undergraduate ones, since many institutions influence the monograph of university education to carry out a field research.

With many projects to review and permeated by controversy due to the variety of the works submitted, many CEP have no way accomplish a more careful analysis or broader plenary discussion, and generally end up using, for research in the humanities and social sciences, the evaluation criteria of biomedical research, more clearly assigned to the specifications of the resolutions of CEP/Conep System. Such uncritical transposition process of submission and evaluation parameters tends to create problems for researchers, besides straining CEP,

which has to revise several times the same research until its approval.

In this sense, the advent of Platform Brazil promises to increase the resolution of CEP/Conep System. However, this tool has been criticized by researchers from various fields of knowledge, because its formatting remains focused on biomedical research, which creates difficulties for researchers in the fields of humanities and social sciences who need to use it. The specificity of the platform reproduces in the CEP, whose sensitivity and knowledge are essential to suggest and accept adjustments in completing the items of the forms provided by the platform, so that you can appreciate projects not from the biomedical areas belonging to large areas of knowledge group III of the title page of Conep: exact sciences and sciences from Earth, engineering, agricultural sciences, applied social sciences, humanities and linguistics, literature and arts. It should also be remembered that, in the implementation process of the Platform Brazil, there was no gradual transition from SISNEP and paper documents to the completely digital format. This led to numerous debates, since many committees were slow to integrate and adapt to the platform, which caused inconvenience to its operating dynamics and to researchers, whose projects remained pending in the system, waiting for assessment by the CEP.

Thus, at present, such controversies led to the discussion of multiple perspectives: many researchers admit the possibility of creating different systems of ethical review in research involving human subjects, while others do not recognize the moral authority of the current ethical system in Brazil, arguing in favor of the individual responsibility of each researcher. The latter group defend that ethics to be considered by researchers must arise from the professional codes of ethics, which often specify best practices and ethical conduct to be exercised within each profession. We believe that the observance and practice of standards expressed in professional codes of ethics are important to any professional in the exercise of their profession and in their scientific practice; this, however, does not replace the social control in research conducted by the CEP/Conep System.

With regard to regulation, it is perceived that the revision of Resolution 196/1996<sup>1</sup>, embodied in Resolution 466/2012<sup>4</sup>, did not bring all the advances expected by most diverse areas of knowledge, which shows that the changes were only punctual, as report Guerriero and Minayo<sup>21</sup>. Perhaps one of the greatest contributions made by Resolution 466/2012 to human and social sciences is the prevision of prepa-

ration of complementary resolution to meet the specific needs of research in these areas. In this sense, in 2013 a Working Group (WG) was created for its development, with representatives not only of Conep, but also from other associations and research societies in various areas of knowledge: Brazilian Anthropological Association (ABA), the National Association for Research and Graduate Studies in Psychology (ANPEPP), the Brazilian Association of Research and Education in Social Work (Abepss), National Association of Graduate Studies and Research in Education (ANPEd), among others<sup>22</sup>. This Working Group held biweekly meetings between February 3<sup>rd</sup> and May 29<sup>th</sup>, 2014, based on six guiding points:

- 1) *include all research on CHS [humanities and social sciences], defined as those based on epistemology and methodologies of these sciences, regardless of subject area or of the empirical issues involved;*
- 2) *be more educational than supervising and controlling;*
- 3) *stick up to the implications and consequences of research practice for the subjects surveyed, without intrusion on methodological and epistemological issues of the projects, subject to review by conventional academic spheres;*
- 4) *recognize different levels of "risk" (or "need for protection"), with different implications for the processing of authorization procedures;*
- 5) *recognize the procedural and dialogical character of the search interface, without inadequate formal requirements for proving a priori the good procedures;*
- 6) *implement a well resumed and agile evaluation system for research with "minimal risk", with the escalation of care in more complex or doubtful levels, to ensure that the system does not become a bureaucratic impediment to the realization research in CHS<sup>23</sup>.*

According to Mainardes<sup>22</sup> over its meetings, the WG developed a *complementary resolution, a form and a guideline of orientation*, which should be discussed by the associations and societies that have integrated, referred to the CNS, discussed in 4<sup>th</sup> National Meeting of CEP (Encep) and made available for public consultation<sup>22,24,25</sup>. We believe that this additional draft resolution has several advances in the areas of human and social sciences under the CEP/Conep System, as no enforcement of written IC and its discharge in appropriate cases, the consideration of various risk levels research and its specification, the distinction between material and immaterial

damage, the ability to vent the CEP/Conep System and strengthening the ethical and methodological review of human and social sciences, taking as parameter their own methodologies of research. However, we believe that the draft resolution lacks clarification at some points, of which we list six: 1) to specify what is considered as different precautionary levels by resolution; 2) to clarify what is considered, in Article 22 of the draft, as "preliminary steps necessary for the researcher to develop his project"; 3) to outline what criteria will be adopted by the CEP for the risk check by CEP's secretariat; 4) to explain that the researcher whose project with minimal risk is chosen to be enjoyed by the CEP should be immediately reported by Platform Brazil; 5) to specify how will be treated the researches located at the interface between the human and social sciences and other areas of knowledge such as the social sciences in health; 6) to define whether this research will answer that additional resolution or those more focused on biomedical research.

It is also important to mention that the research definition involving human subjects from Resolution 466/2012 is very broad, and it is unclear what types of research involving human subjects do not require assessment and which should be reviewed by the CEP/Conep System, which means that this concept also needs to be better specified to solve the doubts that arise in the course of the CEP work process.

As mentioned, in the context of this discussion on the ethical review of researches in the areas of human and social sciences, there is a proposal to develop a specific system for project review of those areas that would be separate from the System CEP/Conep – therefore, unrelated to the Ministry of Health and the National Health Council (CNS) - and linked to the Ministry of Science, Technology and Innovation (MCTI)<sup>11,26,27</sup>. Justifies the elaboration of this new system the impossibility of drawing a supplementary resolution from a resolution of bio-centric perspective<sup>27</sup>. Depending on the argument, we believe that the CEP/Conep System and its resolutions must adapt to the needs of the humanities and social sciences, in order to build a more inclusive model of ethical review of research projects. Therefore, it is necessary a constant updating of these resolutions to social participation through public consultation, which also means recognizing that the revision of Resolution 196/1996, held in 2012, by becoming Resolution 466/2012, fell short of aspirations and needs of much of the scientific community.

Despite the need to enhance the CEP/Conep system, the exclusion of the humanities and social sciences could break it up and distance the academic areas from the so desired transdisciplinarity (understood as a consequence of dialectical synthesis from the interdisciplinary <sup>9</sup>), once it would establish a barrier to the production of knowledge, rather than being a channel of communication between the different ways of doing research. It is important to mention that under the CEP, interdisciplinarity happens through the correlation of referees perspectives from various areas of knowledge in the ethical review and discussion of opinions about projects, while transdisciplinarity would be a step forward, that is, it would mean the recognition of the interdependence between knowledge and the plenary discussion apart from a pretended ideal paradigm of producing scientific work, whether biomedical or not.

In this sense, the elaboration of a complementary drafting of a resolution for the human and social sciences is in line with the statement Diniz and Guerriero that it is not necessary to prepare another system of ethical review. The CEP/Conep system should incorporate the various modes of doing research, given that ethics should be present in all types of research, *but its translation in procedure rules for the committee work should be different* <sup>28</sup>.

Thus, it is essential that the regulation of ethics in research in Brazil contemplate and recognize the existence of multiple forms of doing research and that differences in research methodology of non-biomedical areas do not draw their ethical, scientific and social merit, which should be considered by the CEP in its ethics review and for the proper development of a complementary focused resolution for the human and social sciences. Another equally important aspect is the need to promote awareness of the CEP/Conep System and its members in order to make efforts to review the research in human and social sciences, using as a methodological parameter the method and the proper techniques of these areas. This means that the coexistence of different approaches within the CEP/Conep system is possible, as is the case of the CEP Institute for the Humanities at the University of Brasilia (CEP/IH/UNB), specialized in ethical review of social research and with the mission to think the CEP/Conep System with the lenses of the particularities of social research, and for that restricting their work to qualitative researches conducted with the use of questionnaires, interviews, surveys and observation <sup>29</sup>. According to Diniz <sup>15</sup>, the CEP/IH/UNB is not a space for segregation of human and social sciences, but

instead, a place of ethical review and knowledge production based on the disciplinary neutrality presumption of the CEP/Conep system, which also has the mission to evaluate the limits and potential of the system itself by reviewing research projects in the areas mentioned before.

In addition, the CEP can and should use the potential arising from its multidisciplinary character to perform their functions, employing therefore transdisciplinary approach in plenary discussions and ethical review of projects. Parallel to the progressive consolidation of ethics committees focused on the particularities of the social area in Brazilian institutions, it is important to encourage the entry of professional areas of human and social sciences in the existing CEP, allowing the awareness and the progressive training of its members in the methods and techniques used in these areas.

In addition to creating the possibility of informal transfer of knowledge, it is essential to also invest in continuous training of referees <sup>30-32</sup>, including the representatives of the users, either as regards the recognition of the idiosyncrasies of the humanities and social sciences, either in terms of any other type of research, even biomedical whose peculiarities change substantially with rapid technological changes and growing. The training of members of the CEP can be carried out in four different ways, which, for the best results, should coexist in a complementary manner:

- 1) By the own CEP, through courses available for new referees and training and updating local courses;
- 2) By the national training courses, which are usually carried out in LDL mode (long distance learning) and include peer ethics committees of various states of Brazil, promoting the interaction between members of the CEP from various locations and different realities. Of these, we highlight the I Long Distance Learning Updated Course in Research Ethics, conducted in 2008 by Anis Institute and the University of Brasilia <sup>33</sup>, and the Bioethics Course Applied to Research Involving Human Subjects, sponsored by the Oswaldo Cruz Foundation (Fiocruz) in partnership with Conep and the Ministry of Health and conducted in two versions in 2012 and 2013;
- 3) By the interaction and learning among partners over the discussions in plenary meetings of the CEP;
- 4) By the promotion of scientific events involving the entire academic community. Besides contri-

buting to empower members of the CEP, such events also help to train local researchers, facilitating the submission process of research protocols to the CEP and the researcher-CEP dialogue.

In order to achieve these educational activities for the academic community and continually train referees, the CEP needs that the institution that hosts it funds and provide the infrastructure that enables the promotion of local courses and scientific events, as well as providing conditions so that the judges reconcile the necessary improvements to its activities in the CEP with their working hours (especially in regard to the national courses, which generally have higher workload) in order to prevent cases of evasion and withdrawal of courses. It further suggests that participating in CEP to be recognized by the Higher Education Personnel Advisory Committee (Capes), bringing some bonuses to teachers and programs in which they operate in the form of scores in production reports.

It is also necessary that all institutions that have CEP include the work done in this body as part of the overall workload of the peer, which would facilitate the attendance to meetings and mobilize the plenary discussions. Furthermore, it is essential to create alternatives to support the participation and retention of user representatives in the CEP and to better include them in local and national training courses. Such alternatives could be, among others, the creation of incentives for employers who release their employees who are representatives of users for activities related to the CEP; the development, in more simple and ludic language, of supplementary material for the training courses, focused on the study of problem situations, and/or the creation of specific courses for representatives of users, considering that not all are college graduates.

Finally, it should be noted that the implementation of educational activities for members of the CEP can contribute to the establishment of plural and transdisciplinary vision of ethical review under the CEP/Conep System, allowing ethics committees to also appreciate the research projects of humanities and social sciences, taking into account their peculiarities and enjoying their ethical, methodological and social relevance, without, however, trying to fit them in the biocentric model search. To respond adequately to this challenge, the CEP/Conep System needs to improve the analysis of research ethics, considering that ethics should always be linked to science and its methods, regardless of the knowledge area.

## Final considerations

Given the above, one can see that the creation of new system of ethical review for researches involving human beings would lead to the fragmentation of the existing system, without definitively resolving the problems raised by non-biomedical areas of scientific knowledge. In addition to weaken further participants of the research, such fragmentation would drag on transdisciplinarity, to build bridges between the many ways of doing science, as proposed the bioethical reflection. The expansion and deepening of concurrent CEP/Conep System to incorporate the needs of human and social areas, in contrast, would avoid new division and fragmentation of knowledge, which in no way contributes to the establishment of interdisciplinary benchmarks to facilitate the construction of a more inclusive and just society. This aspect requires the strengthening of the system CEP/Conep in its entirety, so that the performance of adjustments should not be restricted to the resolutions and/or the creation of new complementary resolutions, but pervade the various aspects that make up its operating dynamics including those relating to the institutional level, the training of its members, its educational role, as well as Brazil Platform, which needs to be improved to meet the satisfaction to research that do not fit the model form currently available for online completion on the platform, which is designed for clinical research and drug tests.

It is also noted that single system of ethical review in research does not prevent the creation of CEP focused on research in the humanities and social sciences, such as the University of Brasilia, and that the development of complementary resolution, focused on the particularities of the human and social sciences, represents an important gain for the CEP/Conep System, as it may contribute to settle any doubts that arise during the ethical assessment of research projects in these areas, especially in committees that have friendlier profile for non-biomedical areas. Specific resolution may also disseminate knowledge and provide understanding of the researchers of these areas on the submission process and ethics review of their research projects by CEP, thus facilitating the researcher-CEP dialogue.

In addition, CEP must be more flexible and pay attention not to become plastered and bureaucratic, using the resolutions as "lifeline" and adopting certain way of doing research as the only and true. There are multiple ways of doing research and science, the truth is something that is sought, but nev-

er, in fact, is achieved; because science is not inert, is always moving, changing and questioning itself. And because they are wider and more resolutions that create an endless number of specific complementary resolutions, they will never englobe all questions and situations that arise in the CEP due to the very nature of science and its amplitude. For questions not covered by the resolutions, the ethics committee should discuss the situation without losing sight of it, also considering the ethical and methodological merit, social relevance, the risk-benefit ratio for participants, and, if persisting in doubt, ask the assessment of the research project by an *ad hoc* referee of the project area that raised doubts.

For the CEP to be more flexible and assume the position of supervisor and co-responsible for the projects in question, without acting as a mere bureaucratic censor, to be able to ethically review the submitted projects with resolution and quality, it is essential to form more ethics committees in institutions with large number of research projects in demand of analysis. In addition, each institution that conducts research involving human subjects, whether public or private, must rely on their CEP, and its members must have adequate training to compose it, once it is essential that the increase in the number of ethics committees are linked for improving the quality of their activities. From this it infers that initiatives such as the Training Course in Applied Bioethics to Research Involving Human Subjects, result from the partnership between Fiocruz and Conep, are excellent to provide the necessary qualification of CEP, but at the same time incentive strategies should be created so that the referees of the CEP join and remain in further education and for that to be more accessible to bioethical learning needs of the user representatives.

Moreover, the very CEP/Conep system must create alternatives to encourage attendance and permanence at meetings as well as the efficiency of CEP referees, since it comes to volunteering. Such situations have been identified as a problem by several studies, as they are identified as limiting the activities of CEP. Alternatives to these limitations are: calculation of hours worked in CEP as effective work-

ing hours at the institution; institutional and curricular recognition of the work in CEP, which would count points for career advancement and other scientific merit systems.

Still in the institutional field of operation of CEP, it is interesting to state that Brazil Platform represents an important advance for increased agility and resolution of the CEP/Conep System, not only to improve the monitoring of approved research projects, but also to reduce bureaucracy. However, this platform still needs improvements in its structure, as it is still primarily focused on research in biomedical areas. Hence from it infers that the CEP more focused on research in the humanities and social sciences as well as in many other areas of knowledge that do not follow the biomedical model of research, shall be sensitive to guide researchers in platform formatting of adaptation to the specificities of their studies. This, of course, does not rule at all the need to improve the platform and create different paths on the platform for the various areas of knowledge, but only meets current usage needs of researchers who do not have time to wait for the changes to be made.

Finally, it is important to clarify that the CEP should not be understood by researchers as an ethical filter that is granted the right to determine what is or is not ethical. Instead, CEP must be understood as a body that is concerned with the social and environmental implications of scientific studies, aimed to exercise social control of researches, and also as an additional role remind the scientific community that science is not autonomous. This means that the professional ethics of the most diverse areas of knowledge should not be against the ethics defended by the CEP. Professional ethics and research ethics advocated by the CEP are complementary and should be partners in any research activity involving human beings or in the biomedical field, or in the humanities and social sciences. Therefore, researchers should employ in their practice a continued ethical practice in their research, in which the ethics committee on research does not represent an obstacle to be overcome, but a partner that helps achieve the highest ethical standards.

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