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Research ethics committees in Brazil: a study with coordinators

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Abstract

This study aimed to characterize the Research Ethics Committees in their profile and operationalization. An electronic questionnaire was sent to the 645 existing committees at the time and answered by 129 coordinators. The answers were categorized by frequency and mean of the answers and passed by a statistical test. The results indicated that most of the coordinators had a degree in Biological and Health Sciences, at Masters and PhD levels. The committees had been operating for more than nine years in higher education institutions, with insufficient institutional support. Members were empowered by readings of the Committee's regulations and guidelines. The distribution of protocols was done by subject affinity and the group decision was given by consensus or vote. It is concluded that the committees are consolidated, comply with ethical regulations, but they need to dialogue more with researchers and with the National Commission of Ethics in Research.
Keywords: Bioethics. Ethics review. Ethics committee. Research.

Resumo

Comitês de ética em pesquisa no Brasil: estudo com coordenadores

Este estudo buscou caracterizar perfil e operacionalização de Comitês de Ética em Pesquisa. Foi enviado questionário eletrônico aos 645 comitês existentes à época e respondido por 129 coordenadores. As respostas foram categorizadas por frequência e média e passaram por teste estatístico. Os resultados obtidos indicaram que a maioria dos coordenadores concluíra mestrado ou doutorado em Ciências Biológicas e da Saúde. Os comitês funcionavam há mais de nove anos em instituições de ensino superior com apoio institucional insuficiente. Os membros eram capacitados por meio da leitura das regulamentações e orientações do Comitê. A distribuição de protocolos era feita por afinidade temática, e a decisão grupal se dava por consenso ou votação. Conclui-se que os comitês estão consolidados e cumprem a regulamentação ética, mas necessitam dialogar mais com pesquisadores e a Comissão Nacional de Ética em Pesquisa.
Palavras-chave: Bioética. Revisão ética. Comitês de Ética. Pesquisa.

Resumen

Comités de Ética de la Investigación en Brasil: un estudio con coordinadores

Este estudio tuvo como objetivo caracterizar el perfil y la operatividad de los Comités de Ética de la Investigación. Se les envió un cuestionario electrónico a los 645 comités existentes a la fecha y fue respondido por 129 coordinadores. Las respuestas se clasificaron por la frecuencia y el promedio y se sometieron a una prueba estadística. Los resultados obtenidos indicaron que la mayoría de los coordinadores finalizaron su magíster o doctorado en Ciencias Biológicas y de la Salud. Los comités funcionaban hace más de nueve años en instituciones de educación superior, con apoyo institucional insuficiente. Se capacitaba a los miembros por medio de la lectura de las normas y directrices del Comité. La distribución de los protocolos se realizó por afinidad temática y la decisión grupal se estableció por consenso o por votación. Se concluyó que los comités están consolidados y cumplen con las normas éticas, pero necesitan dialogar más con los investigadores y con la Comisión Nacional de Ética de la Investigación.
Palabras clave: Boética. Revisión ética. Comités de Ética. Investigación.

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Declaram não haver conflito de interesse.

Since the middle of the 19th century, the interest for the relation between Ethics and research has increased in the society and the scientific community. Ethics aims at setting rules and standards that enable a harmonious co-existence, according to Olivé[1]. Both in the international scenario and in the Brazilian context, discussions have been stimulated in different forums; a number of regulating documents have been prepared and actions for controlling investigation activities have been taken by committees and commissions. Experiences accumulated in various ethical assessment systems have revealed in the long run that the self-regulation performed by researchers is not sufficient, so that independent committees focused on social control became a necessity[2,3].

In Brazil, this regulation has been complied with by Research Ethics Committees (Comitês de Ética em Pesquisa - CEP) and the National Research Ethics Committee (Comissão Nacional de Ética em Pesquisa - Conep), which together form the CEP/Conep system. The role of Conep is to foster and monitor CEP's works. Note that even though the proposal of establishing a National Bioethics Council (Conselho Nacional de Bioética) has been discussed in the Brazilian Congress since 2005[4-6]. A significant characteristic of the actions undertaken by CEP relates to its social control character – as proposed since the former 1996 resolution which regulated the sector. A social - and not public - control, as the free exercise of Ethics is assumed to involve independence and no other interests, duress or coercion may exist[7].

Currently, the national ethical guidelines for researches involving humans are defined in Resolution 466/2012 by the National Health Council (Conselho Nacional de Saúde - CNS)[8]. Approved by the Ministry of Health on June 13, 2013, it superseded CNS Resolution 196/1996[9], which had been in force for almost 17 years. Although the more recent resolution did not introduce major changes compared with the previous text, it did include some changes related to the assessment process and CEP operationalization which may provide for ethical assessment that are more relevant to the different lines of research.

The changes that did not generate controversies include: research definition and concept not limited to obtaining generalizable knowledge, formulating hypotheses and sample studies; possibility of obtaining the free and informed consent form (TCLE) *a posteriori* (provided that it is needed and duly justified). Additionally, it presents rules concerning researches in the realm of health sciences in specific items and sub-items and the creation of a supplementary resolution with guidelines and rules that apply to the particularities of researches in human and social sciences.

Ethical assessment has guidelines as its guiding principle, with a main focus on participation criteria, free and informed consent, risk and benefit analysis, participants' rights, researcher's responsibility and qualification, and monitoring of approved researches. CEP work is guided by three aspects. The first relates to delimiting the concept of what will be regarded as researches involving humans: all those which directly or indirectly involve humans, either individually or collectively. The second relates to the level of researchers' qualification: researches outlined by undergraduate and graduate students and professionals should be submitted. The third corresponds to the scope of investigations: researches in all knowledge areas should be assessed[8].

As the CEP expanded, the CNS published guidelines which are available to users of the CEP/Conep system so that they may understand how it works and get assistance for the works developed by the committees. Such guidelines include the "Research Ethics Journals"[10], the "Operating Manual for Research Ethics Committees"[11], and the publication "Qualification for Research Ethics Committees"[12]. CNS has promoted National Research Ethics Encounters to assess and monitor the CEP/Conep system, in addition to having established the Brazil Platform (Plataforma Brasil - PlatBr) to computerize project processing. This platform also allows communication between researchers and Conep and between Conep and the CEP. In short, considering the current interest in Bioethics, as well as in other sectors of knowledge production, the purpose of this work is to investigate coordinators' perception as to how the CEP work, with an emphasis on composition, structure, and operationalization.

Method

The sample was built by CEP coordinators who were included in the list made available by Conep in February, 2012. A total of 129 CEP coordinators from all states in Brazil and from different types of institutions participated. This total corresponded to 27% of the 645 committees that existing at that time[13]. The project was

previously approved by the CEP of the College of Health Sciences of the University of Brasilia. Both the TCLE and the questionnaire were made available on the Internet, and the latter was also completed in electronic medium.

Firstly, contact by telephone was made with committees to which electronic mail could not be delivered. The questionnaire was created by software SurveyMonkey [14] and structured with 41 questions distributed in general lines: professional identity of the coordinators; CEP characteristics, composition, and operationalization; project assessment and relationship with the academic community; and relationship with the institution and Conep. A survey model was applied to the questionnaire as it was adequate to descriptive studies and allowed a survey of the distribution of certain characteristics [15].

Also, it was decided that data would be collected online so as to facilitate contact with the participants by expanding the geographic coverage of the survey, in addition to allowing the interviewed to choose the moment to fill in the instrument, thereby ensuring more spontaneity and adhesion to the survey. A numerical analysis method (absolute frequencies) was used, as well as percentages (relative frequencies) and response averages (in scale) related to the guidelines of CNS Resolution 196/1996 [9] and the guidelines of the "Operating Manual for Research Ethics Committees" [11]. A chi-square test (χ^2) was conducted to statistically assess the relevance of the differences between the answers, with a confidence interval of 5% [16].

Results and Discussion

Professional Identity

Table 1 shows the most frequent answers about the coordinators' profiles. It enables on to determine a professional dominance in the Biological and Health Sciences areas, a higher number of masters, doctors and practicing researchers from higher education institutions, and ages ranging primarily between 40 and 60 years. When age, educational level and experience as a researcher are associated, it is inferred that these people are professionally mature and qualified to perform research activities. The concentration on Biological and Health Sciences is a trend that is verified in similar studies [17-20].

However, generally speaking, the CEP's revealed a diverse academic background, which might indicate better conditions to dialog with researchers from different occupations, including their class and academic representations. Similarly, by getting diversified, the Ethics committees expand the presence of members with different moral perspectives, allowing their work to have new Bioethics references as parameters, such as the complexity theory and the respect for moral pluralism [21]. In contrast to professional maturity, coordination time revealed that most coordinators carried out their first mandate to the end. This may indicate that the CEP's constantly renew its leadership and that there is little experience in works which do not require one knowledge only, but also a continuity of experiences.

Table 1. Identification of the occupation of CEP coordinators participating in the survey

		n	%
Age (in years)	31-40	22	17
	41-50	37	29
	51-60	30	23
	Other	40	31
Gender	Female	64	50
	Male	52	40
	Did not answer	13	10
Educational level	Master's	44	34
	Doctorate	62	48
	Other	23	18
College education field	Biological and Health Sciences	89	69
	Human and Social Sciences	18	14
	Double academic training	5	4
	Exact and Earth Sciences	6	5
	Other	11	9
Researcher	Yes	112	87
	No	6	5
	Did not answer	11	9
Developing research	Yes	76	59
	No	40	31
	Did not answer	13	10
Time as a CEP member (in years)	< 1	7	5
	1-3	38	29
	4-6	37	29
	7-9	19	15
	> 9	15	12
	Did not answer	13	10
Time as a CEP coordinator (in years)	< 1	27	21
	1-3	47	36
	4-6	16	12
	Other	39	31

CEP Characteristics

Table 2 shows the main CEP characteristics pointed out by coordinators. More than half of the Ethics committees (53%) originated from higher education institutions, which may explain - at least in part - the academic degree and the researcher profile of most coordinators. This is also an important input, as it highlights that such committees are part of strategic institutions, since they are responsible for most of the researches conducted in Brazil. Additionally, there is the possibility that the CEP's perform an educational rule to developing researchers, like to the students of such institutions.

Table 2. CEP Characterization

		n	%
Time CEP has been active (in years)	4-6	24	19
	7-9	26	20
	> 9	47	36
	Other	32	25
Time CEP has been active (in years)	North	7	5
	Northeast	18	14
	Southeast	52	40
	South	27	21
	Center-West	8	6
	Did not answer	17	13
Type of CEP institution	Higher Education institution	68	53
	Hospital or the like	37	29
	Other	24	19
Advantages for the institution of having a CEP	Contributes to an ethical conduction of researches within the institution	104	81
	Contributes to the development of ethics in researchers conducted by students and professors	89	69
Advantages for the institution of having a CEP	CEP fails to monitor approved researches properly	67	52
	Lack of institutional support to CEP operations	43	33

The questions relating to the advantages and disadvantages of an institution having a CEP allowed the selection of more than one answer alternative. From the available options, the most quoted advantages – *Contributes to an ethical conduction of researches within the institution* and *Contributes to the development of ethics in researchers conducted by students and professors* – demonstrated that, from the coordinators' perspective, it is advantageous for the institution to have a CEP which assesses researches and performs an educational role. The disadvantages that were more frequently quoted – *CEP fails to monitor approved researches properly* and *Lack of institutional support to CEP operations* – are problems that were pointed out since the establishment of the CEP/Conep systems, including as a impairment for committees to act with moral responsibility in research development [8,22]. As the ethics committee is composed by members who perform voluntary work, the assignment might not be met due to the lack of time. Also, the lack of institutional support goes against the guidelines, which set forth that such organizations should ensure a proper structure for the CEP's to operate [8].

CEP Composition and Operationalization

The regulation applies to committees not only because of the number of their members but also their multidisciplinary composition [8]. Most answers showed that the CEP's have between 11 and 15 members (35%) and between 16 and 20 members (18%). Considering all the CEP members, their academic background is diverse: out of the 369 answers, 92 members (25%) said they were from the Biological and Health Sciences area, 82 (22%) from the Human Sciences area, 73 (20%) from the Social Sciences area, 66 (18%) from the exact sciences area, and 56 had no academic degree (15%).

The academic areas of the members, as informed by the coordinators, differ from those observed in other studies [17-20], where most professionals were identified to originate from the Health and Biological Sciences areas. In said study, this area is also the greatest absolute number, but still very close to that of Human and Social Sciences which amount to 155 members altogether. When a predominance of members from a certain knowledge area is verified, the ethical assessment perceptions and procedures focused on the concepts of a given field are maintained. This could turn the committees' assessment and decisions biased and poor.

It is also necessary that the CEP's discussions and decisions manage to aggregate, in addition to the contributions from different disciplines [23], the Bioethics principles that guide the regulation [24]. All the CEP's meet the guidelines as to the presence of a social control representative, the majority of which comprises users of the institution, civil society organizations, and health system users. The operation of such representative is often incipient as he or she is not aware of the processes involved in the research, but ensures the CEP/Conep system a democratic representation of the collectivity [25].

As for Brazil, representation by social control is a right ensured by the Federal Constitution [26]. The expression is used in public administration with such a meaning as to indicate that people may oversee the Government's actions in public management and when making administrative decisions [26,27]. A higher qualification of social control members is possible and desirable, depending largely on the organization of sectors that are external to the CEP's and the institutions to which they belong. Ethics committees select their members according to rules that allow appointment by pairs and represent various sectors of the institutions (69%); however, in some of them, the members are appointed by the institution itself (12%).

A contribution to improving the process of selecting CEP members is to prepare a profile for such members [17]. On the other hand, coordinators are chosen mainly from the members of the CEP itself (73%), which denotes that they work with the sought-after freedom related to the institutions to which they belong. However, it is remarkable that 11% have pointed out that such members are appointed by institution superiors. The appointment of coordinators by the institution superiors was found in other researches [17,18], which may represent a risk to an independent work and generate conflicts of interest when assessing researches.

Almost half of the members remains at the CEP for a period ranging from one to three years (40%), that is, for just one mandate. This implies an expressive loss of acquired experience by the CEP's, since that a significant part of the members is not retained. The performance of Ethics committees requires constant improvement, and one of the elements for it is the members' experience in assessing researches and exchanging ideas and knowledge over time [19,20]. Such rotation of professionals requires that training processes are constantly initiated, in addition that it prevents the group from maturing.

This is a crucial point for a successful committee performance, as it is considered that the mandate time (limited to three years) provides the experience that contributes to build more comfort to panelists when assessing researches and to greater unity in the results of this work. Meetings were predominantly held on a monthly basis (63%), which is compatible with the requirement of issuing consolidated written opinions within thirty days [8]. A consultation conducted on the websites of various committees has shown that a monthly meeting is held in most of them. Proposing a higher frequency for the meetings might be counterproductive or even discouraging to the members given the voluntary nature of the work.

Regarding the number of projects assessed in 2011, intervals *of less than 50* and *between 50 and 100* got 19% of the answers each, and *between 101 and 200* got 15% of the choices, without material statistical differences among the alternatives. The low demand for assessment protocols would be positive, for instance, because it allows members to analyzed the same research. Therefore, this would enable a more complete and effective assessment from the ethical and multidisciplinary perspective, and the CEP could attain the interdisciplinarity proposed by the guidelines [8].

A great demand for protocol analysis, on the other hand, would detect an excessive volume of work, denoting that many projects are being assessed per month. A large amount of protocols would impair more careful assessments, which might run the risk of turning the process into a simple checking of procedures. In this context, a meeting would be the moment to attest the opinion submitted by the panelist and would fail to generate discussions and more refined assessments. Conep recommends that opinions should not be just a document to be approved or rejected, but rather undergo an assessment in which all the panelists of the committee would participate [11].

A study produced by Oliveira [18] has shown that 50% of the members interviewed used just a checklist when assessing researches, which could indicate a superficial review. However, in order for the CEP assessment to be more efficient, other factors should also be taken into account. The following factors might contribute to improve CEP's performance: the number of members, the time they dedicate to the committee's activities, and even the number of administrative staff and equipment available. These aspects influence the processing of the projects and, consequently, the assessment itself.

The key monitoring mechanism for approved researches is the partial and final reports (55%), followed by visits (10%), which result primarily from complaints. Yet, the expressive number of coordinators (19%) pointed out that there is no sort of project monitoring conducted by their committees. If, on the one hand, the workload of the CEP's may be reduced by reorganizing and resizing the committees, on the other, the issue of monitoring approved projects goes beyond that, as it would also involve having researchers willing to be monitored.

Although that is set forth in the guidelines as a task the committees are supposed to perform, there are no specifications regarding how such monitoring should be conducted [28,29]. It is essential

to note, however, that the experience of the authors of this study – whether as Conep members, CEP coordinators or members having attended meetings and workshops with the CEP from other institutions – shows exactly the opposite: most researches are not followed up by the CEP's simply because their members do not have enough time nor logistic support for that.

The initial training of members has proved to be very diverse, especially for *clarification of CEP operationalization by the coordinator and secretary* (64%), *reading of CNS Resolution 196/1996 and supplementary regulations* (64%) and *reading of the CEP Operational Manual* (57%). This diverges from Freitas e Novaes' study [17], which identified that most of the qualification was self-learned. Qualification, in particular of new members, requires careful and diverse work.

The continued educational activities that were selected the most – *thematic discussions during meetings* (48%) and *participation in events on the subject* (45%) – contribute to improve the work done by the CEP while serve as a forum for discussions and knowledge production, instead of being devised just as an assessment instance [30]. Initial qualification and continued education activities allow the CEP's to develop their own voice. Developing the members' capacity for reflection to assess research protocols is an ongoing task and depends heavily on institutional support.

Project Assessment and Relation with the Academic Community

As reported by the coordinators, the assignment of projects to panelists (reviewers) is primarily done based on thematic affinity (43%) and randomly (22%), which confirmed by the work produced by Hardy and collaborators [19]. The purpose of the ethical assessment by the CEP's would be more successful if each member could assess any kind of research, for which an 'ethical eye' would the key tool, supported by the guidelines that regulate researches. However, a project may be composed by a series of elements involving a particular method or specific procedures that could be incomprehensible to a reviewer from another area.

So, reviewing by subject affinity provides reviewers with a safer ground and balances the rigor involved in research assessment and availability, a concern that permeates the work of the committees [31]. In 53% of the CEP's, all members assess projects, whereas in 28%, not all do: because 17% of the members are beginners, 6% are not researchers, 5% prefer not to do it, and the remaining 19% stand for non-respondents. The limitation preventing new members from assessing projects is a transitory situation and shortened by qualification, but the member's unwillingness to assess would require more attention, since it was not clear if that is a punctual or permanent option.

Regarding the application of the regulation guidelines, 28% of the coordinators stated that there are no difficulties. However, all the difficulty options presented were pointed out: *research method assessment a* (22%), *assessment of quantitative ad qualitative researches according to the same criterion* (22%), *assessment of high and low-risk researches according to the same criterion* (17%), *assessment of the interest conflicts related to researchers from the institution* (12%). No significant statistical difference was verified. The difficulties that were informed are in line with the inquiries by researchers about the research assessment process, like the TCLE requirement for any type of research and the monitoring of approved researches.

In the future, it will be necessary to investigate if any difficulties resulting from conflicts of interest are really reduced, or if for any reason they have escaped the attention of researchers and the CEP itself. When analyzing the effectiveness of the instruments regulating research ethics, Lorenzo [32] relies on Habermas' regulatory theory and communicative rationality. It relates to theories that should be used by democratic societies as a way of social emancipation from sectors with greater economic power. To this end, public discussion forums should be created where all those involved in the issue to be regulated would be represented. In the scenario of Brazilian democracy, the CEP's are the forum for those discussions.

Such considerations demonstrate the relevance of reviewing the guidelines set forth by CNS Resolution 196/1996, which took place between September, 2011 and September, 2012 and culminated in the establishment of CNS Resolution 466/2012. Although the review was carried out through Public Consultation between September and November, 2011 [33] so that the different segments involved could be represented (researchers, users, and the entire CEP/Conep system), a few inquires are questioned. The little information on the consultation process, the little time for an actual participation and centralization of proposals in the hands of a few people from Conep prevented the Public Consultation from reaching is potential audience.

Also, the maintenance of the bioethical theory of the four principles (autonomy, beneficence, nonmaleficence and justice) as a conceptual basis to the Resolution is especially questioned as well. Instead, a wider reference could have been elected which, in addition to expanding the biomedical and biotechnological scope of the document, could also consider social and human sciences – areas which frequently generate conflicts in the CEP/Conep system. In this respect, the incorporation of the Unesco's *Universal Declaration on Bioethics and Human Rights* (*Declaração Universal sobre Bioética e Direitos Humanos* - DUBDH)[34] – of which Brazil is a signatory – as the epistemological foundation of the Resolution would provide a significant expansion of its field of action. That's because it would then incorporate areas which are not covered by the above-mentioned restrictive, principle-oriented current.

According to the data collected in this study, the submittal of the panelist's opinion to the collegiate was done by reading it, discussing it and then a group decision was rendered. Collegiate assessment means that the group of members should open up to the discussion of he different ethical concepts and look for balance among the diverse perspectives, group agreement and ethical guidelines. Coordinators stated that they saw the CEP as an assessment instance by pointing out the collegiate work of the committees, as well as the routine compliance with guidelines and technical procedures[35].

These responses confirmed the dialogic nature of the meetings and the search for an agreement in ethical assessments of research protocols involving reflection and decision making both at individual and collective level. The relations established between the CEP members become an element of recognition of otherness and subjectivity[34,36,37]. Therefore, when performing an ethical review, the assessor judges and makes his or her decision based not only on ethical guidelines, but also the way of absorbing such rules. Such absorption is permeated by the reviewer's ethical and moral concepts, which are impregnated with the senses and meanings that built his or her subjectivity.

The resolution of the controversies involving researches and opinions occurs, as stated by 42% of the coordinators, with discussions and searching for an agreement, whereas 25% stated that i occurs by submitting favorable and contrary arguments. Most of the choices made by coordinators stress the collegiate nature of the CEP's, where discrepancies are discussed and the people involved try to reach a solution that meets the predominant trend in the group. Even though the assessment work is associated with a rapporteur member, it is the fruit of a collective effort, which demonstrates that the CEP's performs its tasks in line with the Conep's guidance[11].

The development of the opinion starts from the ethical guidelines and by using the tools of Bioethics and the elements thereof, the key elements of which are dialog, negotiation and, finally, decision. The opinion originates from two levels of dialog: an internal level, carried out between the CEP members, and an external level, with the researcher, that is, as a communication element that structures itself in discourse. A discourse originated from Bioethics cannot rely just on the theoretical models that oriented the preparation of national and international ethical guidelines. In other to analyze this conceptual field, it is necessary to make use of broader analytical tools, such as DUBDH[32], Bioethics of intervention, and Bioethics of protection.

Garrafa and Lorenzo[38] favor the qualification of committees for assessing researches in social vulnerability contexts, a key aspect that is defended by the Bioethics of intervention, by incorporating this new insight on Bioethics to their analytical tools and methods. Schramm[39] relies on the limitation of principialist Bioethics and proposes other references, such as the Bioethics of protection, for an ethical analysis in contexts where population inequality is involved. There is little discussion in the literature about research assessment other than the bioethical references and legal implications.

The heart of this discussion is generally the protection of the participants together with the responsibilities of those who promote and execute the research. An example of that is the seven requisites regarded by Emanuel[40] as universal, applicable to any research regardless of its context, which aspect is highly questionable according to the theoretical Bioethics currents with roots in Latin America. Such universal requisites include: research value, scientific validity, fair subject selection, favorable risk-benefit balance, independent assessment, free and informed consent form, and respect to the subjects included in the research.

The committees assessed all kinds of researches in 2011, in particular field researches (69%), researches using secondary data (66%), epidemiological survey (53%), and case study/case report (53%). Hence, the committees are required to be constantly improving regarding conflicts and ethical concerns, the ethical implications of the

many researches methods, obtaining TCLE in various contexts, and other specificities of the various kinds of research. This is particularly relevant when a new member is welcomed, for whom the mere presentation of the regulations and the corresponding application are not the required training.

It is considered that project assessment in partnership with more experienced members might represent effective learning as it allows the new member contact with the activity performed by the committee without overloading the older members. Thematic discussions during the meetings also enrich the CEP's work continually and without depending on greater investments by the institutions to which they relate. Another element that demands careful appreciation by the CEP's refers to the impact of the different research approaches on the participants.

As assessors lack theoretical and methodological knowledge on a number of research fields, the assignment of projects by thematic affinity, as already mentioned above, provides members with more safety and may ensure more consistent assessments for the different types of research. The qualification of members should thought not only related to their knowledge of the guidelines, but also as to the moral judgment and decision making. The fruit of the CEP collegiate work and the consolidated opinion may not be designed just as the outcome of the sum of different opinions that converge to an agreement (which is not always possible).

The opinion arises from the reflections of each subject and his or her decisions, which will be assessed by his or her peers in the production of a work that needs to be collective. More than the result of a multidisciplinary understanding, CEP's assessment should be regarded as having an interdisciplinary nature. Another aspect that should be considered in our discussion is that it is always advisable that the CEP's submit processes which involve very specific themes and methodologies and escape the safe domain of the Committee towards a reputed expert – the *ad hoc* referees.

Regarding researcher service, the coordinators have pointed out that they are available at the times disclosed by the committee (31%), at a scheduled time (14%), and through email (16%), or using those options together (18%). In 21% of the questionnaires, the coordinators did not answer this question. This may denote that they failed to classify the working routine of their committees according to the options given in the questionnaire, but it may also mean that in some cases coordinators are not available to support researchers. This kind of issue requires more attention.

The high rate of in-person service may result from the presence of the committee in the research institution and this seems to be positive feature to stress the importance of a dialog between the CEP and the researchers, since ethical assessment is still understood by many as a coercive or punitive action. On the other hand, the use of emails is a way of expediting the contact between the parties, enabling the CEP to process the assessment more efficiently, in particular after the implementation of PlatBr. A reduction of the assessment time by the CEP/Conep system is a frequent claim by researchers, who complain about the delays in their research schedule [41-43].

Researchers get support primarily from administrative staff (53%) and coordinators (44%). Based on the assumption that both have extensive knowledge about the procedures that research projects go through, they may contribute to turn CEP's operation more visible to and acknowledged by the academic community as a supplement to its educational role. In 43% of the CEP's researchers are not supposed to attend meetings, whereas in 22% of the committees such attendance occurs upon request of the collegiate to clarify doubts about the project.

A closer contact with researchers might be a way of strengthening the committee, cause the work to be more transparent, and allow researchers to be familiar with the procedures their project will go through, as well as the points considered in the assessment of their research. Such proximity should be regarded by the committees as strategic and as a contribution to ethical researches and the ethical development of professors and students. It must be observed that contributions to an ethical conduction of projects and the development of professors and students in Ethics and research were regarded by over 80% of the coordinators as an advantage of having a CEP present in their institutions.

The disclosure of CEP activities, according to 56% of the coordinators, is more frequent through the institution's website. This may be understood as a way of bringing the committee closer to the academic community and break resistances by clarifying the purpose of the CEP/Conep system and the role of the CEP's, in addition to promoting reflections on Ethics and research. A crucial issue in the work developed by CEP relates to the procedure carried out when a nonapproved research is developed. In the CEP that have been analyzed, two approaches stood out: *notifying the researcher and asking for the suspension of the research* (32%) or *notifying the institution and asking for the research to be suspended* (19%). It is noticeable that the higher frequency was attributed

to the lack of answers, since 33% of the coordinators did not reveal their opinion.

According to the guidelines, it is CEP's scope and responsibility, in situations where ethical irregularities affect researches, to ask the institution management for conducting an investigation. If the occurrence is eventually proven, the CEP is also responsible for informing this to Conep and other instances, as the case may be[8]. Such occurrences require that the CEP take a concrete action, as the researcher has committed Ethics violation, as well as sensibility in its decision on how to handle the situation.

They also require the committee to maintain its objectives, so that such handling is not regarded by the academic community as a police action or just an investigation action. The fact that one third of "nonresponses" is not taken into account suggests that committees play a mediating role and clearly demonstrates that this is a difficult question to handle. This may occur due to failures in detecting the issue or the lack of a procedure defined by the CEP. This is also a pending issue that requires in-depth investigation.

CEP, the Institution and Conep

It was questioned how CEP gets institutional support for its work and how it relates to Conep. The only type of compensation identified covers members under an employment agreement with the institution, who are assigned a schedule to perform their tasks. Such practice meets the recommendation to release the member from his or her duties when working for the committee, ensuring autonomy and independence at work[8]. Here we find a discrepancy in the idea of voluntary work, especially because when one assesses a project, one is working for the institution to which the committee belongs, and the committee's value is not just a subjective one.

In 34% of the cases, no schedule whatsoever is assigned; in 22%, meeting time is paid, and in 16%, the members are paid for the meetings and for preparing opinions. It would be highly recommendable that higher education institutions fully recognized the participation of professors in the CEP and retributed their voluntary dedication. Such retribution could be done both as compensatory time or considering their participation in assessments for stepping up to higher positions in the university, which rarely occurs. The participation of members in events, such as congresses and courses, for instance, helps improve CEP's operation and depends on incentives from the institution.

In 25% of the CEP's studied, coordinators are sponsored to participate in events, but in 22% of the committees there is no sort of support whatsoever. Sponsorship from the institutions to improve CEP's works is not provided for in the regulation; however, there is a practice of reimbursing expenses with transport, accommodation, and meals when incurred in the performance of CEP tasks[8]. Participation in events may be regarded as a CEP task, since it represents a good opportunity of continued education as well as an exchange of experiences with other committees.

Most of the CEP's have their own facilities (64%), own staff (57%) and the required equipment (58%). The proper operation of the committees requires fixed facilities, recognition by the community it serves, specific personnel to perform administrative tasks, furniture and communication, IT and office equipment, just to name a few. The lack of such structure would impair the work and limit the specific operating organization that would ensure the adequate processing of research protocols, including ensuring the confidentiality of research information.

For most coordinators (67%), the relation between Conep and the CEP's is limited to submitting informative documents on a regular basis. It is noted that this choice indicates a relation which is guided by bureaucratic procedures for assigning instructions. The poor frequency of the other responses signals the Conep's failure to perform a satisfactory work, like promoting events to discuss research Ethics (16%) and qualification (10%). Due to its role as an articulator and manager of the CEP/Conep system, Conep is regarded as being responsible for improving its educational role by offering regular Ethics and research qualification courses and fostering frequent events to CEP members. Also, Conep is responsible for encouraging that the CEP's get closer to one another and to the Committee's technical and executive teams.

Final Considerations

The data collected point out that committees comply with the regulation, have an adequate structure, manage to communicate with researchers, and work on a dialogic basis. However, criticism and complaints from researchers persist related to the research progress and the research assessment

process itself. Despite the criticism referred to in this study concerning some content issues, CNS Resolution 466/2012 and CNS Resolution 510/2016, the latter being specific to the Human and Social Sciences [44], are expected to contribute to solve some of the problems found since the establishment of the CEP/Conep system.

In addition to such changes, it would be desirable that Conep built a permanent forum to improve the system. This forum would encompass all the people involved with research development: CEP/Conep systems members, society representatives, Bioethics experts, researchers, research promoters, funding agencies, and various sponsors. It is considered that dialogic communication is the primary took to exchanging ideas, expanding knowledge and accepting CEP's works in assessing researches in Brazil.

More visibility to the work performed by the CEP's and Conep is necessary, to the same extent that this structure and its operating process should be recognized as political forums for discussions and decisions. The regulation related to a multidisciplinary composition and the social control of Ethics in researches are important elements for this task. However, it is only with the awareness and ratification of society and a partnership with the academic community that said task could be recognized at a political level. After all, national councils and their different instances were established by public authorities to solidify actual social and democratic participation.

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Referências

. Olivé L. Epistemologia na ética e nas éticas aplicadas. In: Garrafa V, Kottow M, Saada A, organizadores. Bases conceituais da bioética: enfoque latino-americano. São Paulo: Gaia; 2006. p. 121-39.
2. Tealdi JC. Historia y significado de las normas éticas internacionales sobre investigaciones biomédicas. In: Keyeux G, Penschaszadeh V, Saada A, coordinadores. Ética de la investigación en seres humanos y políticas de salud pública. Bogotá: Unesco; 2006. p. 33-62.
3. Freitas CBD. Os comitês de ética em pesquisa: evolução e regulamentação. Bioética. 1998;6(2):189-95.
4. Barbosa SN. A bioética no Estado brasileiro: situação atual e perspectivas futuras [dissertação]. Brasília: UnB; 2010.
5. Oguisso T, Schmidt MJ. O exercício da enfermagem: uma abordagem ético-legal. 3ª ed. Rio de Janeiro: Guanabara Koogan; 2013.
6. Goldim JR, Francisconi CF. Os comitês de ética hospitalar. Bioética [Internet]. Porto Alegre: UFRGS; 1995 [acesso 31 dez 2010]. Disponível: http://bit.ly/2lnrBhO
7. Hossne WS. A regulamentação da ética em pesquisa. In: Fortes PAC, Zoboli ELCP, organizadores. Bioética e saúde pública. 3ª ed. São Paulo: Loyola; 2009. p. 95-110.
8. Brasil. Conselho Nacional de Saúde. Resolução nº 466, de 12 de dezembro de 2012. Aprova as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União. Brasília, n. 12, p. 59, 13 jun 2013, Seção 1.
9. Brasil. Conselho Nacional de Saúde. Resolução nº 196, de 10 de outubro de 1996. Aprova diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Diário Oficial da União. Brasília, n. 201, 16 out 1996, Seção 1.
10. Brasil. Conselho Nacional de Saúde, Comissão Nacional de Ética em Pesquisa. Publicações. [Internet]. 2007 [acesso 10 fev 2013]. Disponível: http://bit.ly/2meH9DU
11. Brasil. Conselho Nacional de Saúde, Comissão Nacional de Ética em Pesquisa. Manual operacional para comitês de ética em pesquisa. 4ª ed. Brasília: Ministério da Saúde; 2007.
12. Brasil. Conselho Nacional de Saúde. Capacitação para comitês de ética em pesquisa. Brasília: Ministério da Saúde; 2006.
13. Brasil. Conselho Nacional de Saúde, Comissão Nacional de Ética em Pesquisa. Mapas de CEPs. [Internet]. 2012 [acesso 10 fev 2013]. Disponível: http://bit.ly/2k7mX2d
14. SurveyMonkey [Internet]. 1999 [acesso 10 abr 2011]. Disponível: http://svy.mk/1kjh7vm
15. Babbie E. Métodos de pesquisas de survey. Belo Horizonte: UFMG; 2005.
16. Sokal RR, Rohlf FJ. Biometry: the principles and practice of statistics in biological research. San Francisco: W. H. Freeman; 1969.
17. Freitas CBD, Novaes HMD. Lideranças de comitês de ética em pesquisa no Brasil: perfil e atuação. Rev. bioét. (Impr.). 2010;18(1):185-200.
18. Oliveira MLC. Comitê de ética em pesquisa no Brasil: das bases teóricas à atividade cotidiana: um estudo das representações sociais dos membros dos CEPs [tese]. Brasília: UnB; 2001.
19. Hardy EE, Hebling EM, Bento SAF, Osis MJD, Pádua KS. Relatório final da segunda etapa do projeto de avaliação do sistema CEP/Conep. Campinas: Cemicamp; jun 2009, v. 1. (mímeo)

20. Bento SAF. Funcionamento dos comitês de ética em pesquisa no Brasil [tese]. Campinas: Unicamp; 2010.
21. Garrafa V. Novas fronteiras bioéticas: ética no mundo global: uma perspectiva do Brasil. In: Anais do X Forum of National Ethics Councils of the European Commission; 11 out 2007. Lisboa: EGE--NEC; 2007.
22. Freitas CBD, Hossne WS. O papel dos comitês de ética em pesquisa na proteção do ser humano. Bioética. 2002;10(2):129-46.
23. Araujo TCCF, Negromonte MRO. Equipe de saúde: vinculação grupal e vinculação terapêutica. In: Franco MHP, organizadora. Formação e rompimento de vínculos: o dilema das perdas na atualidade. São Paulo: Summus; 2010. p. 73-100.
24. Schramm FR. Aspectos cognitivos, metodológicos e morais do trabalho dos CEPs. In: Carneiro F, organizadora. A moralidade dos atos científicos. Rio de Janeiro: Fiocruz; 1999. p. 53-9.
25. Hamel MR. Da ética kantiana à ética habermasiana: implicações sociojurídicas da reconfiguração discursiva do imperativo categórico. Rev Katálysis. 2011;14(2):164-71.
26. Brasil. Constituição da República Federativa do Brasil, de 5 de outubro de 1988. Brasília: Senado Federal; 2002.
27. Brasil. Ministério da Transparência, Fiscalização e Controladoria-Geral da União. Portal da Transparência. [Internet]. Controle social. [s. d.] [acesso 14 fev 2013]. Disponível: http://bit.ly/2fQLdoT
28. Freitas CBD. O sistema de avaliação da ética em pesquisa no Brasil: estudo dos conhecimentos e práticas de lideranças de comitês de ética em pesquisa [tese] [Internet]. São Paulo: USP; 2007 [acesso 17 jul 2012]. Disponível: http://bit.ly/2kLoH35
29. Kipper DJ, Santos AG. Sistema gerencial de acompanhamento de protocolos de pesquisa envolvendo ensaios clínicos. Rev. bioét. (Impr.). 2007;15(1):141-53.
30. Lima WM. Bioética e comitês de ética. Cad Ética Pesqui. 2004;6(14):23-8.
31. Lagonegro ER. Uma experiência exemplar. Cad Ética Pesqui. 2001;4(8):9-12.
32. Lorenzo CF. Los instrumentos normativos en ética de la investigación en seres humanos en América Latina: análisis de su potencial eficacia. In: Keyeux G, Penschaszadeh V, Saada A, coordinadores. Ética de la investigación en seres humanos y políticas de salud pública. Bogotá: Unesco; 2006. p. 167-90.
33. Brasil. Conselho Nacional de Saúde. Consulta pública sobre Resolução 196 segue até o dia 10 de novembro. Informativo eletrônico do Conselho Nacional de Saúde [Internet]. 20 set 2011 [acesso 25 set 2011];8(28). Disponível: http://bit.ly/2kWvysH
34. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração universal sobre bioética e direitos humanos. Brasília: Unesco; 2005.
35. Brussino SL. Antecedentes y fundamentos de la ética de la investigación [Internet]. [s. l.]: Unesco; 2006. [acesso 20 jul 2011]. Disponível: http://bit.ly/2mc350D
36. Durand G. Introdução geral à bioética: história, conceitos e instrumentos. São Paulo: Loyola; 2010.
37. Tacca MCVR. Além de professor e de aluno: a alteridade nos processos de aprendizagem e desenvolvimento. In: Simão LM, Martinez AM, organizadores. O outro no desenvolvimento humano: diálogos para a pesquisa e a prática profissional em psicologia. São Paulo: Thomson Pioneira; 2004. p. 101-30.
38. Garrafa V, Lorenzo C. Ética e investigación clínica en los países en desarrollo: aspectos conceptuales, técnicos y sociales. Córdoba: Unesco; 2006.
39. Schramm FR, Palácios M, Rego S. O modelo bioético principialista para a análise da moralidade da pesquisa científica envolvendo seres humanos ainda é satisfatório? Ciênc Saúde Coletiva. 2008;13(2):361-70.
40. Emanuel E. ¿Qué hace que la investigación clínica sea ética? Siete requisitos éticos. In: Lolas F, Quezada A, editores. Pautas éticas de investigación en sujetos humanos: nuevas perspectivas. Santiago: Programa Regional de Bioética OPS/OMS; 2003. p. 83-96.
41. Pessalacia JDR, Fernandes G, Cury PM. Percepção de acadêmicos de medicina e enfermagem quanto à importância do comitê de ética em pesquisa. Rev. bioét. (Impr.). 2010;18(1):213-23.
42. Ramos DLP, Junqueira CR, Puplaksis NV. Benefícios da avaliação ética de protocolos de pesquisas qualitativas. In: Guerriero ICZ, Schmidt MLS, Zicker F, organizadores. Ética nas pesquisas em ciências humanas e sociais na saúde. São Paulo: Aderaldo & Rothschild; 2008. p. 193-205.
43. Sociedade Brasileira para o Progresso da Ciência. Leis para pesquisas em seres humanos é tema de encontro da Conep. Jornal da Ciência. [Internet]. 15 jul 2010 [acesso 6 maio 2016];4053. Disponível: http://bit.ly/2lSBbZI
44. Brasil. Conselho Nacional de Saúde. Resolução nº 510, de 7 de abril de 2016. Dispõe sobre as normas aplicáveis a pesquisas em Ciências Humanas e Sociais. Diário Oficial da União. Brasília, n. 98, p. 44-6, 24 maio 2016, Seção 1.

Participação dos autores
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