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Research Ethics committees' leaderships in Brazil: profile and performance.

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Resumo O artigo apresenta resultado de pesquisa voltada a definir o perfil das lideranças do Sistema CEP-Conep, bem como as percepções desses atores sobre o sistema. Trata-se de estudo transversal, com aplicação de questionário com perguntas predominantemente fechadas. Discute a representatividade, a presença de gestores institucionais; o excesso de trabalho para seus membros; e a necessidade de melhor formação em ética em pesquisa. Destaca as áreas consideradas mais complexas pelos entrevistados, tais como pesquisas que envolvam crianças, povos indígenas, genética, novos medicamentos e procedimentos considerados invasivos. Constata aspectos positivos, concluindo que o dispositivo CEP-Conep é estruturado e no mais das vezes efetivo. Por fim, identifica riscos de conflitos de interesses, necessidade de maior democratização nos CEP e participação de representantes de usuários, aspectos relevantes para o desenvolvimento da política de proteção de sujeitos de pesquisa no Brasil.

Palavras-chave: Comitês de ética em pesquisa. Ética em pesquisa. Revisão ética. Bioética.

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Currently, regulation of research involving human beings is part of public policies and social practices in countries governed by democratic regimes, and it aims at expanding citizen's rights – specifically, in this case, research participants. Changes in scientific and technological general practices boosted research regulation, in addition to insert itself in public policies expansion movement, as well as by growth in medicine and its presence in daily health services practice.

In developed countries, it became mandatory to submit previously research projects to ethics committees, which are analyzed in their specific context features viewing accepted ethical benchmarks [1]. In recent years, influence that profile of members of these committees exerts on their daily practices and decisions has been studied, since specific local ethical benchmarks and regulation



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application take place through decisions where context must be considered always[2,3].

In Brazil, approval of Resolution 196, *Guidelines and Regulatory Norms for Researches involving Human Beings*[3], by the National Health Council (CNS), in October 1996, defined Latin America pioneer public policy, and implemented by the development of an evaluation system for research ethics. The system based in relations built with government and society's representations, in social ordaining defined in the 1988 Constitution, and, specially, its concept of community participation, which is one of the Unified Health System (SUS) guidelines. Research Ethics committees (CEP) and the National Commission for Research Ethics (Conep) were proposed to be *real ethical-political discussion laboratories for emerging technologies*[4], which would set effective social control on scientific practices, qualifying them from ethics stand point, trying to avoid inducing, imposition, exploitation of society's most vulnerable, exposition to useless risks and foreseeable damages.

It is possible, from a structural and organizational perspective, to consider this policy implementation phase completed, as it arrived 2010 with 596 CEP in activity[5]. It is important, right now, to apprehend organizational dynamics key-features of this regulatory system, aiming at getting subsidies about Research Ethics evaluation practices and its articulation with health care and management. Under this perspective, it is significant to know executors of this practice in Brazil and, specially, their leaderships, opinion makers participating in CEPs who contribute to legitimize decision-making in commissions [2]. Thus, the objectives of current work were: 1) to know actors and leaders' profile in Research Ethics control system, from people nominated by the CEPs to comprise Conep; 2) to know their self-evaluation on their performance; 3) to know the perception that they have about current practices

in the system, defined in regulamentation [6].

Method

A cross-sectional type study was undertaken, using questionnaires with predominance of closed questions. A list comprising 188 individuals, nominated by CEPs in August/2003 for election, by CNS, of 12 new Conesp members, according to CNS Resolution 196/96, was interviewed. These individuals comprise a group that is qualified with high esteem in their institutions, been nominated by their peers, which allows to classify them as acknowledged leaderships.

After sending the invitation and free and clarified consent term, 117 (62%) of nominees consented in receiving the questionnaire, while 45 (38%) preferred to reply by mail, and 72 (62%) by electronic means, adding up, in the end, to a total of 94 valid responses, coming from 79% of total nominating CEPs. Geographic distribution of responses corresponds to 80% of CEPs in the Southern region, 77.9% from the Southeastern region, 77.8% from the Northeastern region, 87.5% from the Center-Western region, and 55.6% from the Northern region. Among the nominees, 30 were CEP coordinators at the time of contact (July/2005). The group of respondents was similar, for some known features, to the group of nominees: 46% were physicians among nominees, and 42% among respondents, 39% were females among nominees and 49% among respondents.

A questionnaire designed by authors was used for data collection, and it was applied as a pre-test in a CEP comprising four parts: I – personal characterization, including sociodemographic, type of formation, institutional insertion and experience in research and Research Ethics features; II – self-evaluation, with items that tried to evaluate performance level, motivation and satisfaction, in addition to difficulties and preferred was of deepening; III – perception about current practices in the system and procedures recommend in norms, in addition to suggestions for improvement; IV – case studies on routine situation in research involving human beings[7]. This article corresponds to analysis of responses of parts I to III of the questionnaire. Open responses were grouped in subcategories, classified by similarity. Simple frequencies described results accordingly.

Procedures to ensure Research Ethics were the free and clarified consent term, anonymous questionnaire, commitment of returning results to participants and project approval by CEP at the Clinics Hospital of the University of Sao Paulo Medical School (HCFMUSP).

Results

Personal Characteristics and self-evaluation Table 1 summarizes part I results, related to these leaderships' personal characterization, gotten in accordance to four dimensions: sociodemographic features, education, institutional insertion and experience.

Table 1 – Leadershps' characteristics of the Research Ethics evaluation system

Dimensions	Main results
Sociodemographic Characteristics	
Gender	49% female; 51% male
Age	67% are between 40 and 59 years old
Religion	81% profess a religion
Education	
Undergraduate studies	74% in biological and health area; 17 % in humanities area; 2% in exact sciences area, and 7% with no reply
Graduate studies	70% with PhD, post-doctorate or assistant professor
Bioethics in education	6% in undergraduate studies and 15% in graduate studies
Continued Educatioin in bioethhics or research ethics	64% yes, out of which 61% in courses organized by academic institutions, 13% by pharmaceutical industry, and 26% others
Institutional insertion	
Working place	71% work at higher education institutions (public and private)
Posts	48% have executive posts at the institution, while 18% in post linked to research and 2% referred as users1 representatives
Experience in reseach and research ethics	
CEP Participation	99% participated in CEP, 42% as coordinators, 60% analyzed 1 to 3 projects/month; 50% with dedication of up to 14 hours/month; 30% analyzed 4 or more projects and dedicated 15 or more hours /month
Participation in other instances linked to research and/or ethics	18% participated in rights protection groups, 14% in professional ethics councils, 58% in research nucleus, 18% specifically in clinical research nucleus
Research experience	93% participated in research in the last 10 years and 26% in new medications researches; 55% received financing from CNPq and Capes, 18% from international agencies and 21% from industry

Regarding self-evaluation of own participation in CEP, questions were made related to understanding on the nature of CEP social representation; satisfaction in task performance and ways to prepare for Work (data not presented in table). Responding about whom CEP should represent, almost 90% understood that CEP

should represent research subjects, simultaneously checking for other groups, that is, 38% judged that CEP should represent local society, 36% professionals and scientists, 34% patients and, still, about 15% judged that CEP should represent managers.

As main motivation to be in CEP, 48% refer To protection of research subjects rights, 22% need to collaborate with the research institution, 6% advocated researchers' interests, and 17% for other reasons. Out of 75% who wanted to continue participating in CEP, most quoted reasons were the possibility of professional enrichment, continuous learning in research and in ethics, social relevance of work in institution and gratifying experience.

Autodidact predominated among ways referred as most important in preparation to work in CEP: 56% indicated readings, experience in CEP; 18.9% referred to knowledge of Resolution 196/06. Additionally, 15.6% indicated participation in courses and seminars, and 3.1% considered that higher education gotten out of undergraduate and graduate studies. Table 2 presents preferred ways to improve work in CEP. Table 3 presents topics identified as of greater difficulty in project evaluation.

Table 2 – Preferred ways to improve work in CEP, from 1 to higher until 4 for least preference

In which way do you consider that your work in CEP could have been improved?	Scores No. of responses					
	No scores	1	2	3	4	Total
Coursrs	9	32	22	19	12	94
Cases and topics discussion	3	36	30	17	8	94
Bibliography and specífic sites guidance	12	25	18	14	25	94
Meetings, seminars with other CEPs	2	54	20	10	8	94

Note: non-excludent variábles.

Table 3 – Greater difficulty areas in projects evaluation

Areas or issues in projects analysis	Number and percentage of those who checked score 1 (greater difficulty)	
	Nº	%
Researches in specific areas or procedures (children, genetics, indigenous people, new medications, too invasive procedures)	36	38.3
Adequacy of follow up and ways to compensate for damages to reserach subjects	30	32.0

Continue

Continued from Table 3

Adequacy of biological material discharge or keeping	28	29.8
Presense of conflict of interests	27	28.7
Analysis, sharing and research outcomes use procedures	22	23.4
Issues related to research interruption and completion	22	23.4
Analysis of research subject decision-making conditions (vulnerability)	21	22.3
Respect for research subjects privacy	20	21.3
Risks and benefits balance for research subject	19	20.2
Comprehension of research design and methodology, and their ethics implications	18	19.1
Need and adequacy of TCLE	18	19.1
Ways to select subjects and inclusion/exclusion criteria, and their ethics implications	15	16.0

In a general evaluation about what participation in a CEP meant, 57% considered as rewarding, 15% referred that increase in prestige within institution and 6% stated negative judgments. Many replies indicated to be hard work, however rewarding, to participate in a CEP.

Perceptions on CEP/ Conep System

About the CEPs in which they participated, issues on structure, functioning, projects analysis and decision-making processes were included.

Table 4 – Perception on functioning of CEP to which they belonged

Aspects of CEP functioning at the institution	No.	%
Regular meetings are undertaken (biweekly, monthly and bimonthly)	90	96.8
Average attendance of members in meeting is greater or equal to 50%	82	88.1
CEP members chosen by nomination	67	72.0
Coordinator chosen by election among members	65	69.9
Generally, decisions are consensual or by vote if there are divergences	77	82.7
Users' representative works as reporter	53	57.0

Concerning periodicity of meetings, 96.8% of interviewed defined them as regular, and for 76.4%, as monthly; 17.2% biweekly, and for 3.2%, bimonthly. Members' participation in

meetings ranged from 50% to 75% for 52.6% of interviewed, over 75% of attendance for 35.5% of them, and in less than 50% for 10.8%.

The large majority referred choosing CEP members by indication (72%), presentd more often by the boards of institution or area (head of department, for example), by CEP coordinator or by other CEP members. Only 22 (24%) reported as been elected by members. It was found that, for coordinators, 70% were elected by members; 23% indicated by boards, and the remnant, by other groups. To improve new members selection process, between 20% to 30% of interviewed highlighted the need of criteria for candidates' profile, preparation of elections, and previous preparation of future CEP members.

Table 5 presents perceptions related to ways to deliberate in CEPs. It concludes that CEPs in which 31 of interviewed participated did not have experience in getting Conep opinions, probably because they did not receive projects for special topics areas... Out of 63 with this experience, nine referred divergence with National Commission's opinions, which corresponds to 14.3%.

Table 5 – Perceptions on CEP decison-making

Aspects of CEP decision-making	*Yes* .º %
Did Users' representative contribute to CEP decisions?	62 66.7
Did human sciences professionals (Law, Philosophy, Anthropology, Sociology, Theology etc.) contribute to discussions?	86 92.4
Were CNS resolutions taken in account in project analysis?	87 93.5
Was there opportunity for cases discussion in your CEP?	89 95.6
Do you remember of cases when there was non-approved project by CEP or that CEP requested major changes in the initial protocol presented by researcher?	90 96.7
Do you think that CEP decisions were respected in your institution?	84 90.2
At receipt of Conep opinions Conep, did diverging points between CEP and Conep become evident?	9 14.3*

* Among 63 respondents whose CEP received Conep opinions.

The most indicated suggestions related to functioning of the CEP/Conep system as a whole, provided by 67 out of 94 participants, were: improvement in communications between CEP and Conep, including improvement by electronic means, seminars conducted to increase system integration, process speed, and decrease in deadlines.

Still, it was evidence that, 95.5% believed that their CEP complied with expected role to protect research subjects, and other 4,3% referred to difficulties, mostly for not following projects after approval.

Discussion

To describe and to study characteristics of these actors and their experiences in CEP/Conep System allowed us to know the dynamics of system functioning in compliance to established regulation, its strong and weak points. These individuals indicated by CEPs, which shows recognition of its competence in the area and representativeness capability at national level, characterizing a leadership role. Regulation does not force them into been a CEP member, current or past ones, or its coordinators. However, out of 94 respondents to the list of nominees, 21 were coordinators, at the time, out of 40 (almost half) of those who had worked as coordinators, reinforcing leadership profile of the group. They are individuals who in certain way stood out in their dedication to research ethics, therefore, opinion makers, and key informers about the system.

Among factors that, in interviewee's perception, contribute to nomination, the following stand out: experience in CEP; interest in bioethics and knowledge about research; personal qualities such as commitment, responsibility, and ethical positioning; participation, communications skills or esprit-des-corps.

Preponderance of professionals from health and biology sector reflects predominant presence of committees in health sector institutions. Among these leaders, presence of about 20% of human sciences professionals points to active participation, suggestion adhesion to needed multidisciplinary in CEPs and Conep members nomination, as recommended in the norms. High proportion of medical professionals in studied group (44%) points to acknowledgement of traditional institutional leadership, evidenced in CEP composition worldwide, as referred in searches headed by Campbell in the USA [8] and Valdéz in Mexico [9], as well as Hardy [10], Goldim [11] and Kipper [12] in Brazil.

Besides equalitarian participation regarding gender, a clear feature of these leaders was academic qualification: two third had doctorate title, well above the 40% ration quoted by Hardy among CEP collaborators. However, few had academic training in ethics or bioethics, noticing that training took place in short duration courses, often sponsored by the pharmaceutical industry, evidencing need to offer deepened and critical training.

It showed a small presence of users' representatives in the group, just four were presented as such at the initial roll, and two among respondents, although there was not ratio indication for this group presence in CEPs, estimated in 9% (average of 11 members with one users' representative) [13]. Laymen and outsiders participation in the

institutional organization of collegiate is recent. In this context, they stand out rarely as leaderships in CEPs, due to diverse and complex reasons, personal (theirs or of other members) and institutional.

Institutional managers' direct participation in committees stands out, inclusively with attributions in research area. As they are responsible for investment policies and fund-raising for scientific activities, their participation in committees may imply conflict of interests, given responsibilities of the position they are in. Such conflicts may include a trend in financial and academic interest accommodation of institution, and compromise of CEPs independence [14,15].

The survey showed a very significant participation of researchers (93%) from many areas, in addition to important participation of professional linked to pharmaceutical trials, showing trend similar to that found in Canada [16] and the USA [8], where Campbell found among professors participating in CEPs, 71% were from clinical research, and 50%, advisors to industry. Possible conflict of interests must be considered evidently, given the context of growing participation in Brazilian centers of international multicenter studies.

The interviewee revealed large experience in CEP participation. Since one third refer analyzing four or more projects/month, dedicating 15 or more monthly hours, the question is if such load would mean an excessive weight, in view of other professional responsiblities. Some of the interviewed reported that the excess of workload constituted a disincentive factor to continue in CEP and about quality of reviews. Increasingly heavier workload has been also considered as an explosive problem in international literature, implying increase in number of professionals refusing to participate in these activities. There are already in other countries proposals to limit this type of research to be submitted to CEPs, and analysis rationalization according to project characteristics and risks [15].

Generally, involvement in CEPs was classified as somehow rewarding, showing a trend of positive perception in 90% of responses, contrasting to recent findings by Valdez, of lack of motivation among participants in CEPs [9]. The profile of interviewed allowed us to confirm group relevance as actors experiencing intensively in practice research ethics control system.

Two questions stand out in discussing results of self-evaluation: representativeness concept and the need of training in research ethics. Comprehension by interviewed about CEP mission to protect research subjects, and perception of participating in a democratic forum in local social environment seem to be mixed. Almost 90% of interviewed mentioned that CEPs should represent research subjects, although not exclusively, have been simultaneously check other

group: professionals and scientists, patients, and managers. Only one third judged that CEP represented local society, a perception that is close to the view of CEP as local instance of deliberative democracy, working in behalf of institutional community and its users, as Guttman theorizes [17].

Most represented groups (institutional managers, researchers linked to pharmaceutical industry or other areas), among leaderships, presented a profile different from originally thought during norms preparation phase, as reported by Marques [18], who had more neutral multidisplinarity ideas as basis, to ensure opinions consistence, and hegemony limitation of one professional category, avoiding biases and conflict of interests. This cause the norm to explicitly prohibit in CEP to have a majority of just one professional category, and participation of at least one users' representative, without other specifications for representativeness or parity[3]. An undeclared representativeness of certain groups was shown in practice. Actually, the issue of representativeness is not clear in any norm, and political discussion on democratic features or procedures in committees in Brazil has not been presented in literature.

Bioethics has been qualified as pluralist, but philosophers and theologists' contributions, from diverse lines, had in its development are well acknowledged. Nonprofessionals' participation in ethical committees is frequent in practice in many countries. This work identified a theologist among nominees, while 49% considered religious influence in their ethical judgment practice is a significant data.

Despite training to participate in CEP derived from autodidact activities, majority of interviewees considered themselves as prepared and competent, in addition to be motivated for the task, Areas mentioned as of greater difficulty in research analysis, which implies specific technical knowledge, were related to projects including children, genetics, indigenous people, new medications, invasive procedures. This may mean difficulty in identifying ethical issues, particularly in protocols whose technical description is complex. Other indicated difficulties show issues complexity when compared to those quoted in the USA two decades ago, mostly referring to consent term[19]. Preferred ways for improvement show interest in active and integrating methodology.

CEP functioning indicators, like periodicity and frequency of members at meetings, may point to the quality of ethical evaluation of protocols, and system capability to fulfill its mission. Very few CEPs were mentioned as not having regular functioning (3.2%), questioning its real need. CEP biweekly meetings in significant number of responses (17.2%), in parallel, may point to a very high demand, compromising the quality of evaluation.

Absence of members in meetings is a relevant event: about 10% reported attendance bellow 50%, a feature that is not approached in norms, but which may compromise multidsiciplinarity, representativeness or coorporativism neutralization.

The way to choose a coordinator has meaning in understanding committees democratization and independence level and adherence to norms, which recommend coordinator's election by members that is not reality lived by one fourth of interviewees, where choosing took place by indication of the institution board. It is possible to infer from some responses that, once the coordinator initially indicated, he defined himself the composition of CEP collegiate, a reversed path to recommendations by the national guidelines.

Users effective participation reveals also committees democratization level and it show a common difficulty, since around 30% of respondents perceive this participation as low contribution, due to lack of technical knowledge and users' representatives weak performance, either because of absence in meetings or by passive attendance.

Users' low participation may indicate difficulty in acknowledging participation of users' community members about in the institution by remnant members. Objectively, 40% mentioned that users' representative was not requested to report projects in their CEPs, which does not contribute to deepening knowledge of protocols and to learn through practice, a situation found also in other Brazilian study[20]. A more active performance of these members would provide capacity to CEPs in evaluating conflict of interest and values among the several actors better. As Schramm[2] highlights, lay members are in good position to judge research projects from general public standpoint and, specially, vulnerable groups' interests.

In Brazil, factors related to lay members participation in committees have not been studied yet. Difficulties are related in other countries committees, regarding intimidation feelings from academic scientific community, in addition to lack of education and training, according to representatives own complaints[22]. One considers as worsening this situation the fact that participation, in general, is restricted to the sole person of this group in majority of CEPs of Brazil.

CNS resolutions were considered always in case appreciation, indicating effective implementation of public policies to protect research subjects from the National Health Council, coordinated by the National Council of Research ethics, while actual opportunity for discussion within CEP scope. However, about 10% of interviewees did not remember major changes in protocols, proposed in CEP meetings, and about 10% of them considered that committees' decisions were not respected always in institutions, factors that, along with checking

for divergences with National Commission opinions, point to the need of capacity-building for researchers and system's participants.

Interviewees highlighted two features to improve choosing members: previous preparation and setting of criteria for candidate's profile of CEP members. Certainly, this reflects difficulty faced, may be consequence, still, of small number of professionals with deepen preparation in research ethics or bioethics, currently composing CEPs. In addition to increased communication with Conep, undertaking of meetings that provide CEP integration and progress in its members' capacity building stood out in suggestions by members of studied group, including events that would allow exchange of experience between CEP and Conep. In interviewees' responses, the need of structural improvement is clear, while followed by demand for modernization of system communication, through initial and continued capacity building for members, for access to information and facilitated contact with the National Commission, which imply greater investment in all levels by institutions. These suggestions seem feasible at the short and medium terms, and they could subsidize priorities definition to support the system. In some of the interviewees' perception, human sciences projects would need differentiated genetics approach. Specificities on qualitative analysis of projects have been advocated [23], despite CNS guidelines scope.

Conclusions/recommendations

Study of research ethics committees' leaderships allowed some conclusions on its profile and the perceptions of its members, picturing the real research ethics control policy, initiated since 1996:

- These leaders' professional formation (indicated for the National Commission) is similar to the set of CEP members, except for the small nomination of users' representatives, an event that may be pointing toward institutional difficulties to identify or to recognize this leadership;
- Leaders have high motivation and compromise, high academic qualification and experience conformed in CEPs and in institutions. Specific formation in Bioethics, in short duration courses, outside undergraduate and graduate formal curricula, requires offer of deepened and critical formation opportunities, exempt of formation sponsored by specific involved groups biases. They stressed the necessity for continued preparation for committees' members, preferably with cases and topics discussions, during peers meetings, when areas with greater difficulty of analysis have been identified;
- One may point toward effective system implementation and integration with CNS resolutions utilization about research ethics based in CEPs decisions, and may recommend discussion of lesser concordance between CEP and Conep

when there are protocols analyzed in both instances;

- There is diverse comprehension about representation and CEPs, frequent nomination of professionals exercising positions, and risks of conflict of interest. Suggestions for curricula criteria and pre-requirements (of attendance, as research ethics capacity-building or of absence, as not exercising executive positions) for CEP members' profile should be considered, in addition to better preparation of the foundations in social control practice;
- Democratization in CEP functioning deserves attention, when responses are jointly analyzed regarding users' representatives performance, election of members and coordinators, and meetings normal quorum. The presence of larger number of users' representatives in CEP may be reinforcement factor of their participation capabilities and for better consideration of their participation, in addition to contribute to independence and equity in considering scientific community and external community standpoints

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Final considerations

The thematic cutting and methodology enabled to identify that CEP/Conep System is structured effectively and it counts on experienced, self-confident, and interested actors. In addition, the study allowed identifying difficulties and discrepancies regarding norms in CEP operationalization, reflecting the need of progress in democratization and caring to ensure committees independence.

Consideration of stressed features, in educational activities and in regulation itself, may lead to reinforce independence and equity in considering scientific community and external community standpoints, particularly those of the Unified Health System users, contributing to effectiveness of research subjects' protection in Brazil. Still, it can be pointed to the need of new studies related to lay members participation, as well as deepening of others that explore the dynamics in CEP formation and its working, taking into account committees varied typification.

Work originated from research to prepare the thesis The evaluation system of research ethics in Brazil: study of committees leaderships knowledge and practice in research ethics, *defended at the University of Sao Paulo (USP) Medical School in 2/23/2007. The article complements already published data in* Revista Bioética *007; 15 (1): 101-116, in a work intitled* " Posicionamentos de lideranças do sistema de avaliação da ética em pesquisa no Brasil – consensos e divergências (Positioining research ethics evaluation system leaderships in Brazil-consensus and divergences)".

Resumen

Liderazgosde comités de ética en pesquisa en el Brasil: perfil y actuación

El artículo presenta resultado de pesquisa dirigida a definir el perfil de los liderazgos del Sistema CEP-Conep, así como las percepciones de esos actores sobre el sistema. Se trata de estudio transversal, con aplicación de cuestionario con preguntas predominantemente cerradas. Se discute la representatividad, la presencia de gestores institucionales; el exceso de trabajo para sus miembros; y la necesidad de mejor formación en ética en pesquisa. Destaca las áreas consideradas más complejas por los entrevistados, tales como pesquisas que involucren a niños, pueblos indígenas, genética, nuevos medicamentos y procedimientos considerados invasivos. Constata aspectos positivos, concluyendo que el dispositivo CEP-Conep es estructurado y las más de las veces efectivo. Por fin, identifica riesgos de conflictos de intereses, necesidad de mayor democratización en los CEP y participación de representantes de usuarios, aspectos relevantes para el desarrollo de la política de protección de sujetos de pesquisa en el Brasil.

Palabras-clave: Comités de ética en investigación. Ética en investigación. Revisión ética. Bioética.

Abstract

Research ethics committees' leaderships in Brazil: profile and performance

The article presents survey results towards defining the CEP-Conep System profile, and these actors' perceptions of the system. It is a cross-sectional study, through application of a mainly closed questions questionnaire. It discusses representativeness, presence of institutional managers, its members' excessive work, and the need for research ethics better formation. It points to areas considered as more complex by the interviewee, like research involving children, indigenous people, genetics, new drugs and procedures considered as invasive. It finds positive aspects, implying that the CEP-Conep system is organized and, most of the time, effective. Finally, it identifies dangers of conflict of interest, the need for more CEP democratization and users´ representatives participation, relevant aspects for the development of research subjects protection policy in Brazil.

Key words: Research ethics committees. Research ethics. Ethics review. Bioethics.

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