The experience of a Brazilian public university research ethics committee

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Abstract

This paper discusses about the experience of the Research Ethics Committee of a state public university in Brazil, briefly describing its operation and results for five years of work. We raised all the drafts submitted to the committee between January 2006 and December 2010 and enrolled 633 drafts of several courses, ranging from undergraduate research, theses, and dissertations works. The aspects analyzed were identified from the cover sheet of preliminary planning, the views expressed by the committee and the research protocol. Most drafts analyzed was classified as pending, the main reasons were mistakes in the consent terms. By comparing the amount of approvals of preliminary examination by the CEP over the years covered by this study, it was revealed that the committee is acting as a training and educational forum for research practice.

Key words: Ethics committee, Research. Bioethics. Ethics.

Resumo

Experiência do comitê de ética em pesquisa de uma universidade pública brasileira

0 trabalho discorre sobre a experiência do comitê de ética em pesquisa (CEP) de uma universidade pública estadual no Brasil, descrevendo sucintamente seu funcionamento e resultados durante cinco anos de trabalho. Foram levantados todos os anteprojetos encaminhados ao comitê entre janeiro de 2006 e dezembro de 2010 e incluídos no estudo 633 anteprojetos de diversos cursos, que abarcavam desde trabalhos de iniciação científica a dissertações e teses. 0s aspectos analisados foram identificados a partir da folha de rosto dos anteprojetos, nos pareceres emitidos pelo comitê e no protocolo de pesquisa. 86,5% dos anteprojetos analisados pelo CEP foram classificados como pendentes, tendo por principal motivo equívocos no termo de consentimento livre e esclarecido. Pela comparação na quantidade de aprovações de anteprojetos examinados pelo CEP ao longo dos anos abarcados por este estudo foi possível perceber que o comitê vem atuando como instância formativa e educativa para a prática da pesquisa.

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

Resumen

Experiencia del comité de ética en investigación de una universidad pública brasileña

El trabajo diserta sobre la experiencia del comité de ética en investigación (CEP) de una universidad pública estadual en Brasil, describiendo sucintamente su funcionamiento y resultados durante cinco años de trabajo. Han sido planteados todos los anteproyectos enviados al Comité entre enero de 2006 y diciembre de 2010 e incluidos en el estudio 633 anteproyectos de diversos cursos, que abarcaban desde trabajos de iniciación científica a disertaciones y tesis. Los aspectos analizados han sido identificados a partir de la portada de los anteproyectos, en los dictámenes emitidos por el comité y en el protocolo de investigación. El 86,5% de los proyectos analizados por el CEP fueron clasificados como pendientes, teniendo como principal motivo equívocos en el término de consentimiento libre y aclarado. Por la comparación en la cantidad de aprobaciones de anteproyectos examinados por el CEP a lo largo de los años abarcados por este estudio ha sido posible constatar que el comité ha actuado como instancia informativa y educativa para la práctica de la investigación.

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

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The regulation by State official agencies of research involving humans intends to foster the development of scientific research and, at the same time, to expand and ensure citizens' rights. The debate on the need to regulate scientific research comes from verification of cruel experiments practiced by Nazis during WWII [1], as well as later researches in democratic societies, such as the study on syphilis' natural history undertaken in Tuskegee, in the United States, in which poor black people did not get treatment or were treated with heavy metals, even when penicillin had already been discovered [2].

The 1975 *Declaration of Helsinki* was the first international document to propose previous evaluation of research projects by an independent committee. Its three later versions kept intact this proposition. However, the proposal for a previous review by a committee is much older, and it may be attributed to Thomas Percival who formulated such idea in 1803, in his work Medical Ethics [3]. In Brazil, the *Declaration of Helsinki* and the *Nuremberg Code* were the two international references in research ethics applied in preparing Resolution 196/96 by the National Health Council (CNS) [4].

The CNS Resolution 196/96 instituted the CEP/Conep system attributing to this instance the responsibility to previously analyze all research projects to be developed in the country. Additionally to projects analyses, the research ethics committee (CEP) exists to act truly as centers of discussion on bioethics [5]. It is known that the main function of a CEP is to ensure protection of integrity and dignity to research subjects, which enables vetoing researches that are potentially violators of these principles, even if protocols are limited by methodological criteria suitable to expected objectives. Another function of CEP is to improve research, avoiding that research subjects undergo risks originating from a work that is not able to achieve its objectives. Its role as an instructor extends, thus, to researchers in addition to fostering ethical discussions in the community through educational lectures [6].

Research ethics committees are not limited to evaluating bureaucratically if any researcher is following or not the norms or if the fields in a form are correctly filled in or not. The analysis by CEP implies reflection, in partnership with researchers, on the best way to ensure research subjects' autonomy, seeking for resources to inform them better about their rights. It seeks to ensure its freedom of decision, identifying and determining the risks and benefits for each group of interest related to the research. Additionally, it is up to the CEP to investigate research subjects' denouncing of eventual irregularities [6].

In addition to be source of protection for research subjects, it is important to mention CEP contribution regarding its consulting role, particularly as an educational instance targeted to ensure institution researchers' continued training and to promote discussion of ethical features of research involving humans in the community [7].

There are few references in domestic literature of studies related to activities, operation, and productivity of a CEP, considering that Brazil currently has 600 of them registered in the National Research Ethics Commission (Conep). Conep is the highest agency in bioethics analysis of a project, having the role of regulating CEP's operations and of analyzing specifically projects involving the more polemic topics or with participation of vulnerable groups, such as, topics on human genetics, research with indigenous people, research involving new drugs, among others [8].

Knowledge on the experience of a CEP may clarify doubts or suggest operational strategies for other committees, facilitating comprehension of the reason for analyzing a certain pre-project of research by an independent committee, as undertaken in the studies of Fontelles [9], Greco [10] and Kipper [11]. The State University of Pará Research Ethics Committee (CEP/ Uepa) has a crucial role in ethics discussions in the state, in addition to act as a fostering center for the institution's professors. Thus, by analyzing the origin, the situation, and the profile of pre-projects submitted to the CEP/Uepa,

this paper aims at enhancing the committee itself, as well as fostering scientific production with ethical quality.

Method

The survey is characterized as cross-sectional and observational. All pre-projects submitted to the CEP/Uepa between January 2006 and December 2010 were analyzed. Research pre-projects involving animals were excluded from the survey along with those that researchers requested withdrawal of their works from the survey. Before initiating cataloging pre-projects, reading of CEP/Uepa bylaws was undertaken.

In order to catalogue variables, a protocol was prepared that was validated by an initial analyses of 10 pre-projects. This instrument defined the fields for submission date, initial opinion issued by the ethics committee, and classification of work, front sheet data, and faults identified by the committee. Identification of pertinent information of each of these fields was obtained through reading the original copy of the research pre-project filed at CEP/Uepa, in addition to reading opinions on the pre-projects.

For data tabulation, the following software was used: Excel 2007, to prepare data and tables, and Bioestat 5.0, for statistics analysis, in accordance with the nature of variables. Descriptive statistics analysis was applied, informing percentage values of analyzed data. Later, an analysis of the obtained material was carried out, comparing them with the findings in literature.

Results

During CEP/Uepa's Five years of work, 689 pre-projects were submitted for the committee's appreciation, of which 633 had all criteria of inclusion, and they integrated the sample. Pre-projects distribution during the period of 2006-2010 was of 136, 140, 133, 101, and 123, respectively. CEP's initial opinion is found in Table 1. Concerning specification of the scientific works (Table 2), 242 were related to completion of undergraduate studies (TCC); 240 in training completion (TCE); 84 in scientific initiation (IC) and 54 in specialization. There were eight dissertation pre-projects and five related to thesis.

Table 1. Situation of pre-projects submitted to CEP/Uepa by year of submission

Year	Approved	Pending	Not approved	Total
2006	8	115	13	136
2007	4	122	14	140
2008	1	119	13	133
2009	0	93	8	101
2010*	13	97	13	123
Total	**26**	**546**	**61**	**633**

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Table 2. Types of pre-projects submitted to CEP/Uepa by year of submission

	2006	%	2007	%	2008	%	2009	%	2010	%	Total	%
TCE	55	40.3	45	32.2	57	42.9	39	38.7	44	35,8	240	37.9
TCC	69	51	50	34.7	42	31.6	29	28.8	52	42,3	242	38.3
IC	7	5.1	21	15	20	15	19	18.8	17	13,8	84	13.2
Specialization	4	2.9	22	15.7	14	10.5	6	5.9	8	6.5	54	8.5
Masters	0	0	1	0.7	0	0	6	5.9	1	0.8	8	1.3
Doctorate	1	0.7	1	0.7	0	0	2	1.9	1	0.8	5	0.8
Total	**136**	**100**	**140**	**100**	**133**	**100**	**101**	**100**	**123**	**100**	**633**	**100**

Concerning the front sheet data, those 633 works belonged to Conep's classification group, and they did not involve any particular topic; they were mono-centered and they did not involve any medication for the acquired immunodeficiency syndrome (HIV/Aids) or placebo and wash-out treatment.

Researchers training area was distributed as follows (Table 3): Medicine (488-77.1%), Physiotherapy (83-13.2%), Occupational Therapy (27-4.3%), Physical Education (21-3.3%), and others (14-2.1%). Regarding researchers' citizenship, 100% were Brazilians.

multidisciplinary collegiate comprising 45 reporting members from several health training areas: 18 from Medicine, 12 from Physiotherapy, five from Occupational Therapy, and five from Nutrition, in addition to two statisticians, one veterinary physician, and two representatives from the community. Of those, 7 are PhDs, 18 are Masters, 6 are experts, and 14 are academics. There is a close amount of men (22) and women (23).

Concerning pre-projects entry processing, it was established the threshold of 20 projects/ month to be analyzed, and selection was guided

Table 3. Authors' training area of the pre-projects submitted to CEP/Uepa by year of submission

	2006	%	2007	%	2008	%	2009	%	2010	%	Total	%
Medicine	100	73.6	105	75	105	78.2	79	78.2	99	80.5	488	77.1
Physiotherapy	8	5.9	17	12.2	19	14.3	16	15.8	23	18.7	83	13.2
Occupational Therapy	11	8	12	8.6	2	1.5	2	2	0	0	27	4.3
Physical Education	17	12.5	3	2.1	0	0	0	0	1	0.8	21	3.3
Dentistry	0	0	3	2.1	4	3	1	1	0	0	8	1.2
Pedagogy	0	0	0	0	2	1.5	2	2	0	0	4	0.6
Production Engineering	0	0	0	0	1	0.8	0	0	0	0	1	0.15
Phonology	0	0	0	0	0	0	1	1	0	0	1	0.15
Total	**136**	**100**	**140**	**100**	**133**	**100**	**101**	**100**	**123**	**100**	**633**	**100**

Reasons leading to works classification as pending or not approved were: faults in the free and clarified consent terms/TCLE (507-80.9%); methodological faults of the project (453-71.5%); errors in the budget or timetable (254-40.12%); lack or outdated curricula (412-65%); works ethically inappropriate (15-2.3%).

Discussion

Due to increasing developing of research projects at the State University of Pará, it turned out necessary, in 2006, to set up an ethics committee to evaluate submitted projects.

As established by Resolution 196/96, the CEP/Uepa is comprised by a secretariat and a

by the front sheet date in the National Research Ethics System (Sisnep). All research pre-projects are analyzed by, at least, two reporters who must analyze them in two weeks at most and issue a substantial opinion in one week at most after the meeting. Reporters in partnership with the chairman and other reporters are responsible for the decision making related to the research, which may be "approved" (when the Project can begin), "pending" (when there is impeding requirement to start the research) or "not approved" (when there is one ethically incorrect or non-acceptable issue).

Of total initially pending pre-projects during the entire period, 539 (98.71%) were approved after correction of aspects indicated in the CEP analysis. Those remaining, non-approved, were largely due to researchers giving up after the first

opinion, similarly to data found by Novaes [8].

A CEP, in addition to enforcing compliance to bioethical standards in biomedical research also have an educational profile, and its educational role should be targeted at their members, researchers, research subjects, and the community at large. An example of this type of activity are courses on ethics in research with humans – among several that serve this purpose [6].

Additionally, the majority of papers approved only after changes requested by the CEP show another facet of this institution that, by highlighting to researchers the major incurred faults and ethical mistakes, it prevents their repetition in future projects. Statistical difference noticed in this survey reaffirms this role, between the quantity of pending issues from other years when compared to 2010, last year analyzed in the survey (Table 1), in which the larger number of pre-projects was approved –found in the study of Greco *et al* as well [10].

One of the problems that ethics committees usually face is the mystification of its role, since only the condition of a bureaucratic and inspection agency is attributed to it [11]. This occurs because often researchers do not understand the reason their works are not automatically accepted and classified as pending or not approved. However, Resolution 196/96 [4] and the Operational Manual for Research Ethics Committees [6] clearly defined that errors in the front sheet, incomplete methodology or needing minor adjustments, as well as mistakes in the identification of risks and benefits or faults in the TCLE, should get the "pending" classification. Those pre-projects that did not present the research protocol, or that had a protocol that was unable to achieve the objective of the study, or incurred in unacceptable ethical deviation, were not approved. In view of such specifications, it is up to the CEP to undertake an analysis judiciously not only to fulfill normative criteria proposed by these instruments but, mainly, for applying the standard to each case, targeting enhancement of the research and of the researcher himself [12].

TCLE is without a doubt an instrument of major bioethical relevance since, most frequently, it is a source of information that research subject has about what will be done with him and what are his rights and duties derived from participating in the research. Its significant importance comes from the fact that the four bioethics principles by Beauchamps and Childress can be seen in it, such as autonomy, by informing participants' right to give up on the research at any time; beneficence and non-maleficence, when reporting risks and benefits derived from research; and justice, for having established legal rights and that there is equal distribution of risks and benefits by the research groups [13,14].

Concerning mistakes made in the TCLE of analyzed pre-projects, the main reasons that lead to pending or non-approval were related to the extreme flowering writing style or eminently scientific, as well as insufficient explanation about the study. These features are similar to those found by Novaes [8] and Goldim [15], showing that the correct preparation of the TCLE still is researchers' main difficulty. Study by Araújo *et al* [16] suggest that in order to facilitate its construction, the consent term should be built in a narrative way, in daily language using research subject's terminology and, even, with popular or regional expressions.

Another difficulty identified in the assessment of pre-projects submitted to the CEP/Uepa refers to awareness about the importance of using the TCLE by researchers, particularly when research uses medical records or stored material. In these cases, Resolution 196/96 mandates contacting the patients in order to use their medical records. If this is not possible, it is necessary that the researcher demonstrate CEP the results of his attempts so it may be evidenced the impossibility and to evaluate the use of data. Although many researchers believe to be unviable finding research subjects, study by Duque *et al* [17] achieve a rate of 74% of authorization from 155 patients through letters and telephone calls, showing the feasibility of attempting to establish contact with the researched.

It has been seen that faults in preparing TCLE, are the major reason for non-approval of pre-projects submitted to CEP/Uepa. In addition to aforementioned reasons and mostly related to the researcher, it should be highlighted also that, according to literature, it is a common practice among many reporting members to limit analysis of a project to just this instrument, which is highly incoherent with a range of technical and bioethical features that should be analyzed jointly in order to prepare their opinion [17].

Concerning the profile of pre-projects submitted to the CEP/Uepa, it was identified that the majority came from the academic sector, encompassing from training completion works (TCE) and course completion works (TCC) to those targeted to subsidize dissertations and theses. Analysis of pre-projects specifications pointed that the majority was of undergraduate works such as TCE, TCC, and IC. Only 8% refer to graduate course – result similar to the findings by Novaes [8].

As it deals with relatively simple works, classified by Conep as group III (without particular topic), the majority of research pre-projects was coordinated by a professor from the same area of training as the student. This implies in difference related to results found by Novaes [8] and Greco [11], since both analyzed multi-centered Works, belonging to groups I and II in Conep's - classification.

Final considerations

Just as it was intended with the regulation of research involving humans, this study noticed that the CEP/Uepa is of crucial importance in expanding ethical discussions related to research undertaken in the State of Pará. CEP operations manual foresees an educational role in local community by means of lectures. Nevertheless, from this survey it was possible to realize that, by undertaking its role of bioethics guardian, CEP/Uepa does not work only as bureaucratic agency, but rather aiming both to ensure research subject's rights and to contribute in studies outlining and application.

It is possible to infer, therefore, that this CEP fosters the enhancement of researchers and stimulates discussion on research ethics in the academic realm. It was possible to understand, still, that in addition to fomenting this type of discussion among students, CEP/Uepa extends its trainer's role to the faculty members, by enabling and stimulating students' participation in the collegiate, what becomes a major factor for streamlining bioethical knowledge and reflection in the academic realm.

References

1. 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]. São Paulo: Universidade de São Paulo; 2006.
2. Vieira S. Ética e metodologia na pesquisa médica. Rev Bras Saúde Mater Infant. 2005;5(2):241-5.
3. Goldim JR, Francisconi CF. Os comitês de ética hospitalar. Rev. Bioética. 1998;6(2):149-55.
4. Conselho Nacional de Saúde. Resolução n2 196, de 10 de outubro de 1996 [internet]. Aprova as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. [acesso 13 out. 2011]. Disponível: http://www.ufrgs.br/bioetica/res19696.htm
5. Freitas CBD, Novaes HMD. Lideranças de comitês de ética em pesquisa no Brasil: perfil e atuação. Rev Bioét (Impr). 2010;18(1):185-200.
6. Conselho Nacional de Saúde. Manual operacional para comitês de ética em pesquisa. 5ª ed. Brasília: Ministério da Saúde; 2008.
7. Muccioli C. O comitê de ética em pesquisa (CEP) e as publicações científicas. Arq Bras Oftalmol. 2004;67(2):195-6.
8. Novaes MRCG, Guilhem D, Lolas F. Dez anos de experiência do comitê de ética em pesquisa da secretaria de saüde do Distrito Federal, Brasil. Acta Bioét. 2008;14(2):185-92.
9. Fontelles Mi, Carvalho RM, D'Oliveira MS. Estudo analítico do comitê de ética em pesquisa da Universidade da Amazônia. Rev Para Med. 2007;21(2):19-22.
10. Greco DB, Mota JAC. A experiência do comitê de ética em pesquisa da Universidade Federal de Minas Gerais (Cep/UFMG) o 1997/98. Rev Bioética. 1998;6(2):197-201.
11. Kipper D, Loch iA, Ferrari NM. A experiência do comitê de ética em pesquisa da Pontifícia Universidade Católicado Rio Grande do Sul, do comitê de bioética do Hospital São Lucas e da Faculdade de Medicina da PUCRS. Rev Bioética. 1998;6(2): 203-9.

12. Almeida AM, Bitencourt AGV, Neves FBCS, Lordelo MR, Lemos KM, Nuñez GR et al. Conhecimento e interesse em ética médica e bioética na graduação médica. Rev Bras Educ Med. 2008;32(4):437-44.
13. Vieira S, Hossne WS. Experimentação com seres humanos. 2, ed. São Paulo: Moderna; 1987.
14. Silva JAC, Teixeira RKC, Monma CA, Neoffi T. Perfil bioético dos anteprojetos enviados ao comitê de ética em pesquisa da Universidade do Estado do Pará. Rev Bioét (Impr). 2011;19(2):563-75.
15. Goldim JR, Francisconi CF, Mahe U, Raymundo MM. A experiência dos comitês de ética no Hospital de Clinicas de Porto Alegre. Rev Bioética. 1998;6(2):221-6.
16. Araújo DVP, Zoboli ELCP, Massad E. Como tornar os termos de consentimento mais fáceis de ler? Rev Assoc Med Bras. 2010;56(2):151-6.
17. Duque CG, Ramalho DMP, Casali-da-Rocha JC. Termo de consentimento e análise de material biológico armazenado. Rev Assoc Med Bras. 2010;56(5):563-7.

Authors' participation

All authors participated in preparation, grammar correction and review of the article.
Jose Antonio Cordero da Silva, research advisor, prepared and designed the work;
Renan Kleber Costa Teixeira prepared the research and participated in data collection;
Thiago Barbosa Gonçalves also prepared the research and participated in data treatment.

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