

Bioethical profile of pre-projects submitted to ethics in research committees of the State University of Para

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Abstract

This paper aims at drawing the profile of drafts sent to Research Ethics Committee (REC) of the University of Para (Uepa). All drafts sent to REC between January 2006 and December 2010 were analyzed, by applying own research protocol allowing to analyze the four principles of the Principlism Bioethics, as well as secrecy. The analysis of REC/Uepa drafts showed that these tend to respect patient's beneficence and autonomy, while justice and secrecy are the bioethical principles least observed, although an improvement trend has been seen with time.

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

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With the advance of biomedical scientific research, such as use of stem cells, genetic engineering and reproduction technologies, in addition to tests with drugs and vaccines, ethical issues related to research surfaced again aimed at avoiding that atrocities carried out in past (such as in the World War II) would occur again. In Brazil, this bioethical discussion is regulated by the National Health Council (CNS), through the CEP/Conep System and the ethics in research committees (CEP) distributed at universities and other research centers, as well as at public administration agencies ^{1,2}.

These collegiate instances (CEP and Conep) were established to be true ethics-political discussion laboratories on emerging technoscience, qualifying them from the ethics standpoint, avoiding issues such as induction, imposition, exploitation of the most vulnerable in society, exposition to useless risks and foreseeable harms ³.



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Given the growing importance of the CEP/Conep System, this paper aims at outlining the bioethical profiles of pre-projects submitted to the ethics in research committee of the State University of Para (Uepa).

Regulation of research in Brazil

CEPs were proposed in the *Helsinki Declaration 2*, while their characteristics and attributions were defined by CNS Resolution 196/96 ⁴. This resolution incorporated the bioethical principles of beneficence, non-maleficence, justice, and autonomy, in addition to other parameters such as confidentiality, privacy, voluntariness, equity, and non-stigmatization ⁵. In order to have due recognition by the committee, it is necessary that it be accredited by Conep ^{1,6} –assessment carried out by the Internet, in Conep website, shows that in 2010, the country had 596 working Ceps ⁷.

The committees are defined as an interdisciplinary and independent collegiate with the *status of public function*. Such feature is due to the fact of registry and evaluating research involving human beings in Brazil, revealing as indispensable for institutions that undertake these studies, since they are responsible for defending research subjects' interests in their integrity and dignity, contributing, thus, for the advancement of research in consonance with governing bioethical standards ^{1,5}.

In order for a Project to be evaluated by the CEP it must have, in its structure, some basic aspects, such face sheet, project outline, employed methodology, budget, and researchers' curriculum-vitae, as well as the free and clarified consent term (FCCT) ¹. Each of these aspects comprises a range of technical and bioethical characteristics that must be jointly analyzed in a project assuring that it meets the

basic precept of respect for the individual involved in the study. With the existence of CEPs, all these requirements get appropriate attention, what would not exist if only sponsors and researchers analysis were done ⁸.

It should be recorded in the face sheet important data such as the researcher responsible for the project and all other involved researchers. The methodology must be outlined with accuracy and caution as, if not correctly prepared, it may cause unnecessary risks for research subjects. The budget shows if researcher has needed material, as well as expenditures inherent to the Project, enabling to know if there is financing condition for its undertaking. *Curriculum vitae* are a major point, since it allows evaluating if the team of researchers has technical condition to carry out the research ¹.

The FCCT is the most significant document from the bioethical standpoint, as it informs patient on the research content and the risks that he may be exposed, while it is also the instrument through which one analyzes autonomy, beneficence, non-maleficence, and secrecy. According to studies undertaken by Santos ⁹, the greatest reason for non-approval of research by CEPs is errors in FCCT (80%), which occurs mainly because of undue construction of the term.

If, as stated, technical foundation for CEP evaluation bases in CNS Resolution 196/96, it is important to highlight that some of the principles are stated also in the 2010 Medical Code of Ethics (CEM).

CEM Article 100, which establishes that it is voided to physician not obtaining approval of protocol to undertake research in human beings, and Article 101 that mentions obligatoriness of FCCT use, signed by research subject or his legal representative, and still providing due explanations on the nature and consequences of research, while FCCT characteristics are defined in Item 4 of the Resolution, are examples to be mentioned ¹⁰.

In case that participant is a minor, CNS Resolution 196/96 and CEM regulate that, in addition to legal representative's authorization, minor's free and clarified consent is necessary, in as much as of his understanding. This understanding, stressed in articles of the resolution and in the code, shows the importance to preserve autonomy and to assure the non-maleficence to research subject ¹⁰. Secrecy is another point of important of analysis, widely disseminated both in CNS Resolution 196/96 and in CEM Article 73, which voids to physician revealing fact that he might have due to the exercise of his profession, except if due to fair reason, legal duty or consent in writing by the patient.

Above consonance highlighted between CNS Resolution 196/96 and CEM, regarding guarantees to research subjects, not only points toward the necessity to respect these principles in clinical studies, but, additionally, reinforces the importance of guiding students, future professionals and researchers, regarding these crucial points in order to

outline studies that take as starting point bioethical principles and the ethical precepts targeted to ensure participants' dignity.

Resolution of research in Latin America

There are small differences in other Latin American countries regarding domestic resolution, considering that bioethical analysis has its base in international codes (the Nuremberg Code and the Helsinki Declaration). But, the difference is based in existence of two instances that analyze different research protocols: the first is denominated as clinical ethics committee, and its function is to analyze clinical practices and certain types of investigation; the second, denominated as ethics in investigation committee, is similar to CEP, as it presents decisory character over research feasibility and its function is to analyze the protocols of the latter and its commands^{11,12}.

Method

The research is characterized as transversal, observational, and retrospective. All pre-projects of research submitted at CEP/Uepa between January 2006 and December 2010, corresponding to all pre-projects submitted to CEP/Uepa until the beginning of the research were analyzed. Out of 689 projects submitted to CEP/Uepa in the period, 633 were included in the study, excluded two pre-projects whose authors requested their withdrawal, and one pre-project whose author did not accept to sign the FCCT, in addition to 53 pre-projects involving animals.

The study used own instrument, developed by researchers, in which the following aspects were analyzed: autonomy, beneficence, non-maleficence, justice, and secrecy, as characterized by CNS Resolution 196/96 and the *Operational Manual for Ethics in Research Committee*¹, based in the definition of the principle of bioethics, and in the secrecy proposed by Beauchamp and Childress' work¹³. The bioethical principles and secrecy were defined specifically in the analysis and its presence or absence in pre-projects, set by the explicit quoting to attributes inherent to each of them (Table 1), as specified next

Autonomy represents the research subject's right to participate in it in fully informed and voluntary manner, while he may leave without any retaliation. Beneficence corresponds to possible benefits that subject may get with the research. Non-maleficence regards the foreseen risks in research designing, which should be avoided. Justice recommends equal distribution of risks and benefits for researched subjects and for society, in addition to legal part of procedure. Secrecy must be respected both in data collection stage and protocol preservation, also including confidentiality of information and research subject's privacy. To validate the questionnaire, a pilot Project was undertaken in which ten pre-projects were evaluated. From this, the research protocol was restructured.

Table 1 Correspondence between bioethical principles and secrecy and expected content in research pre-projects

Classification	Expected content
Autonomy	Voluntary Participation of research subject Presence of FCCT The right to give up on the research, by the research subjects, even after signing FCCT Absence of mechanisms that may induce research subject to participate in it Justification for choosing vulnerable groups Justification for choosing locality to deliver the FCCT Provide, within their limitations, pertinent information to research for minors of 18 years old
Beneficence	Description of benefits yielded by research Applicability of benefits in practice Benefits are more significant than risks Benefits of interest to research subject
Non-maleficence	Description of risks of research Guarantee of minimizing risks from research Possibilities of permanent harm Absence of risks that may jeopardize research subject's quality of life There is pertinence for discomfort or pain for research subject
Justice	Equal distribution of risks and/or benefits among groups of research Concentration of risks and/or benefits in determined group Guarantee of indemnification provided by legislation
Secrecy	Guarantee of secrecy for the research subject's data, such as name, age, address, among others Destination of data collected in research

Source: Research protocol

For the tabling and analysis of data, the software Excel 2007 for table construction and Bioestat 5.0 for statistical analyses were used, in accordance with the nature of variables. Descriptive statistical analysis was applied, been informed percentage values of analyzed data.

Results and discussion

Due to the growing undertaking of works at Uepa, the constitution of an ethics in research committee (CEP) showed itself as necessary. Its work started in 2006 and, from this period, it began to analyze large amounts of projects,

from completion of stage works (TCE) and completion of course works (TCC) until those targeted to subsidize dissertations and thesis. The analysis of specification of studied projects showed that majority are undergraduate students' work, such as TCE, TCC and scientific initiation, and only 8% refer to graduate studies – similar result was found by Novaes ⁴.

Concerning areas that submitted projects to the committee, it was identified that almost 99% of analyzed works were from the biomedical area. This may be justified by the fact that the CEP/Uepa is located within the Uepa's biological sciences and health campus, as well as by professor in this area, who were researchers and/or research advisors, are more attentive to the requirement of submission to CEP when designing a research project.

Regarding the amount of pre-projects received by the CEP, there was not, in total analyzed months, significant variation ($p>0.05$). However, a slight trend was

noticed in submission of works in the second semester, mostly in August and September. This occurs, probably, due to the fact that completion of stages I, II, and III by Uepa medical students must be presented at the end of 1st, 2nd, and 3rd years, culminating in larger number of submitted pre-projects in the CEP during the second semester. The circumstance of CEP/Uepa not having analyzed pre-projects in December, in 2009 and 2010, contributed for lower amount of pre-projects appreciated in those years –which presented average of 112 pre-projects, when compared to 2006, 2007 and 2008, whose average was 136.33 pre-projects.

Pre-projects analysis evidenced that the percentage average of disrespect to bioethical principles was considered as low, remaining at the level of 21.5% for autonomy, 19.9% for beneficence, 23.6% for non-maleficence, and 39.7% for justice. It was verified also a slight increase in transgression of these in initial years of CEP works, as Table 2 shows.

Table 2 Percentage of works disrespecting some bioethical principles and secrecy. Belem/ PA, 2011

Classification	2006*	2007	2008	2009	2010	Total
Autonomy	22.6%	26.5%	22.6%	16.9%	17.1%	21.5%
Beneficence	31.6%	24.3%	14.3%	13.9%	13.1%	19.9%
Non-maleficence	31.6%	25.8%	15.8%	23.8%	20.4%	25.6%
Justice	67.7%	55.7%	20.3%	24.8%	23.6%	39.7%
Secrecy*	97.8%	92.9%	44.4%	48.5%	29.3%	64.3%

Source: Research protocol ($p<0,01$)



According to Table 2, it was possible to observe that respect to secrecy had a significant increase ($p < 0.01$) in five years, having its transgression rate decreased from 97.8% in 2006 to 29.3% in 2010. This percentage growth for respect to secrecy is due, above all, to the fact that CEP/Uepa fulfilled its educational role in years subsequent to its creation, targeting promotion of discussion of bioethical aspects in research involving human beings in the institution, not having a punitive character as foreseen by the resolution ^{1,2}.

The data in table show also that beneficence was the most respected principle (507 – 80.1%). The main reason for its transgression was total absence of information about the benefits that could exist for researched subjects – what may have occurred because some researchers consider this as a logical principle, and supposing unnecessary to mention in the pre-projects the benefits for research subjects or for society. Such circumstance was responsible for 81.45% in breach of the principle of beneficence within analyzed material.

Another reason for this absence may have its origin in the fact that some researchers mixing the precepts of scientific research objectives – to generate knowledge for society's wellbeing – and remaining focused just in “generate knowledge”, not caring for what it is or for what it may serve.

Autonomy was the second most preserved principle (497 – 78.5%). However, 63.7%

of works did not mention that research subject has the right to withdraw his consent at any time after signing FCCT. Analysis of pre-projects points that the main disrespect to this principle derived from not mentioning this possibility. This generates an ethical problem, since only at the beginning of research, when receiving information and signing FCCT, the subject would have his autonomy respected.

Another significant issue about this principle was the fact that many pre-projects only requested authorization from legal representatives of adolescents from 12 to 18 years old to participate in research, forgetting to inform and request authorization from participants in this age range. It was possible to verify that their autonomy was not considered in 44% of cases. Despite not been legally accountable, the right to knowledge of methodology is assured to them, as well as in participating or not in data collection. In this case, it was possible to notice greater disrespect for child and adolescent's autonomy than of adults. The importance of analyzing possible breach of autonomy lies in the fact that majority of researched individuals belong to vulnerable socioeconomic group ², as they may be inhibited to participate in certain research for not losing any type of benefit.

The finding of a profile respecting more beneficence than autonomy may be justified by researchers' paternalist training, considering that in the health area this is still an



existing reality ¹⁴ – reinforcing, thus, the need of using FCCT to assure research subject's right.

Non-maleficence is a much confused principle regarding its meaning, and it may be defined as not undertaking procedures that may generate physical or psychological loss to patient. This is evident in pre-projects, since every research presents risks to its researched ¹. This is the researcher's role to identify these risks and to minimize them at their maximum. However, the study identified that such attitude was not always followed by researchers in pre-projects, both by not surveying for alternative methods to carry out their research (1.73%) and by exposing research subjects to permanent risks (1.73%). Nevertheless, the major cause for breach of the principle of non-maleficence was not mentioning risks that research subjects could be exposed (89.18%) or, in cases that this was informed, there was not information on how such risk would be minimized (43.75%).

According to the assessment, the reason for transgression of justice lies in the absence of clarification in pre-projects about harms and indemnifications that should be budgeted in case of physical or psychic harm to research subjects (99.19%). Such particularity shows lack of respect for research participants, since researchers did not Record any way of legally minimizing harms caused by undertaking the experimentation.

Justice, in bioethics realm, is in majority of cases interpreted solely as equal distribution of access to health service by the entire population, but actually it presents a very wide concept and it relies in a distributive justice, where, for example, those most in need more support and investment than those less in need ¹³. Thus, in the Field of research with human beings, justice is developed in equal distribution of risks and benefits, and in the fact that it considers what is due to people. Therefore, there is a situation of justice when there is room for benefit to someone that had been jeopardized by acts of another ¹³, becoming mandatory the information to research subject about his right to indemnification.

Secrecy was, among evaluated queries, the least respected, while this is of crucial importance for undertaking any research ¹. Once assured, it allows research subject to develop needed trust to report his personal information, reducing, thus, reporting of untrue data that may yield biases in the research. Lack of mentioning destination of obtained information in the pre-project, preponderant for breach of secrecy (93,8%). Nevertheless, it should be highlighted the significant increase – 3,200% in relation to 2006 and 2010 – no regarding secrecy due to clarification in the FCCT about the destination of collected information.

The progress in this point, viewed in Table 2, is the reflex in awareness of the researched on the need and importance of informing destination

of collected data after completion of research, in the respect for the principles of bioethics in an order that secrecy may be assured both at time of isolated view, may be confirmed at its analysis data collection and after this stage when there is as a set. Thus, one may realize that in the initial still risk, although lower, of exposing information years of the research, disrespect for several of the researched. Once again, one may attribute principles occurred simultaneously (Table 3), this increasing favorable situation to CEP own as there were few works that did not have any work as promoter of the dissemination and bioethical deviation. However, the educational discussion of bioethical principles and of norms work undertaken by the CEP was noticed in for research undertaking. the last studied year in the research: majority of works (74.9%) presented just one or no bioethical deviation

The statement about CEP positive action, which may be verified when one analyzes

Table 3 Percentage of works disrespecting any bioethical principle, Belem/PA, 2011

Disrespect	2006	2007	2008	2009	2010*	Total
Any principle	0.7%	3.5%	35.4%	28.7%	45.6%	21.8%
1 principle	23.6%	27.9%	36%	34.6%	29.3%	30%
2 principles	32.3%	27.9%	14,3%	25.7%	11.4%	22.4%
3 principles	22%	22.2%	9.8%	4%	8.1%	13.9%
4 principles	14%	12.8	1.5%	5%	3.2%	7.6%
5 principles	7,4%	5.7%	3%	2%	2.4%	4.3%
Total	100%	100%	100%	100%	100%	100%

Source: Research protocol (p<0,05)

The bioethics educational work of students principles of bioethics to be respected, since and professors undertaken by CEP/Uepa is of FCCT was not presented in a small number of crucial importance, mainly because it is a projects (1.1%). Despite referring to reduced committee located within a public university, percentage, such omission is considerable as the which has as objective to instruct researcher FCCT is indispensable, inclusively in projects in on bioethics, in such manner as they can carry which patient's data record sheet analysis is out their work, always respecting research undertaken to ensure, thus, the rights of the subjects ⁵. Nevertheless, the study shows researched ¹. that dissemination of knowledge still is necessary in scientific community about the

Table 4 Percentage of respect for bioethical principles and secrecy related to biomedical area courses at Uepa, Belém/PA, 2011

Areas	Autonomy	Beneficence	Non maleficence	Justice	Secrecy
Medicine	80.5%	83.1%	82.5%	65.1%	38.7%
Physiotherapy	80.7%	79.5%	61.4%	61.4%	40.9%
Occupational therapy	70.3%	85.2%	70.3%	37%	11.11%
Physical Education*	61.9%	33.3%	19%	19%	4.7%

Source: Research protocol (p<0,05)

Analyzing the bioethical profile of pre-projects Nevertheless, it should be well in each course (Table 4), those in physical understood that, in current study, the four Education presented the highest rates of basic bioethical principles and secrecy violation both of bioethical principles and were analyzed in the pré-projects secrecy. This may have occurred because submitted to CEP, and one may not infer professionals from this course are more necessarily that proposing researchers involved in education than in health area. present these profiles. Thus, it is Consequently, they have, generally, less necessary a study to evaluate if such contact with bioethics, with principlialism, and situation is coincidental. norms targeted specifically to ensure secrecy, which reflects directly in the pre-projects of the **Final considerations** area.

One study by Tenorio *et al*¹⁵ presents data bioethical notions of responsible rectifying such finding: analyzing ethical researchers. If designed in accordance to variable described in articles of Physical the guidelines set by CNS Resolution Education found that none of articles had 196/96, it should ensure all principlialist mentioned simultaneously the right to bioethical principles, as well as secrecy for anonymity, use of FCCT, and approval in a researched subjects, while CEP is the CEP – few quoted one of these, at least, what responsible agency to assure enforcement shows the necessity of bioethical enhancement of these issues. in their research.

It was not observed statistically significant differences in the other courses, showing that they present similar profile. Pre-projects analysis by CEP/Uepa showed that they present a bioethical profile that respects more beneficence and autonomy as the least respected bioethical principles. However, there was progressive decrease in amount of disrespected principles, showing



the role of CEP in improving bioethical profile. since their reality probably diverge from This not only validated CEP work, but it also that found in current study, due to the fact emphasizes the importance of studies such as that many get different pre-projects this one, which may stimulate continued profile, where there is higher prevalence perfecting of CEP/Conep System, as well as of graduate multicentric studies or clinical professional training in Medicine and other assays financed by the pharmaceutical health areas. industry or research fostering agencies or international organisms.

Still, one must stress the importance of carrying out other research of the same kind, in other CEPs,

Resumo

Perfil bioético dos anteprojetos enviados ao comitê de ética em pesquisa da Universidade do Estado do Pará

Este trabalho objetiva traçar o perfil bioético dos anteprojetos enviados ao comitê de ética em pesquisa (CEP) da Universidade do Estado do Pará (Uepa). Foram analisados todos os projetos enviados ao CEP entre janeiro de 2006 a dezembro de 2010, mediante aplicação de protocolo de pesquisa próprio, que permite analisar os quatro princípios da bioética principialista, bem como o sigilo. A análise dos anteprojetos do CEP/Uepa demonstrou que tendem a respeitar a beneficência e a autonomia do paciente, mas não contemplam na mesma medida a justiça e o sigilo, apontados no estudo como os princípios bioéticos menos respeitados; contudo, com o passar dos anos, houve melhora gradual dos princípios e do sigilo.

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

Resumen

Perfil bioético de los proyectos enviados al Comité de Ética en Investigación de la Universidad del Estado de Pará

Este trabajo tiene como objetivo trazar el perfil de los anteproyectos enviados al Comité de Ética en Investigación (CEI) de la Universidad del Estado de Pará (Uepa). Se analizaron todos los proyectos presentados al CEI/Uepa entre enero de 2006 y diciembre de 2010, aplicando su propio protocolo de investigación, que permite analizar los cuatro principios de la Bioética Principialista y la confidencialidad. El análisis de los proyectos del CEI/Uepa demostró que tienden a respetar la autonomía y la beneficencia del paciente Dejando de contemplar en la misma medida la justicia y el sigilo, apuntados en el estudio cómo los principios bioéticos menos respetados. Sin embargo, hubo una mejora gradual de los principios y del sigilo en los últimos años.

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

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Authors participation

All authors participated in designing and reviewing of this article. Jose Antonio Cordero da Silva designed the research and guided the work; Renan Kleber Costa Teixeira designed the research and participated in data collection; Cristiane Akina Monma and Tatiane Neotti participated also in data collection.