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Research Ethics Committee of the University of São Paulo Nursing School: experience of the first six years

COMITÊ DE ÉTICA EM PESQUISA DA ESCOLA DE ENFERMAGEM DA USP: EXPERIÊNCIA DOS PRIMEIROS SEIS ANOS

COMITÉ DE ÉTICA EN INVESTIGACIÓN DE LA ESCUELA DE ENFERMERÍA DE LA USP: EXPERIENCIA DE LOS PRIMEROS SEIS AÑOS DE FUNCIONAMIENTO

Maria Cristina Komatsu Braga Massarollo¹, Paulina Kurcgant², Maria de Fátima Prado Fernandes³

ABSTRACT

The aim of this study was to know the experience of the first six years of the Research Ethics Committee (REC) of the University of São Paulo Nursing School activities. The exploratory, descriptive, retrospective and quantitative study analysed the records of the REC and of all the 401 research protocols submitted for appreciation from 31st August, 1998 to 17th September, 2004. The results showed that 98.7% of protocols were from in-house researchers; 31.4% were master degree dissertations and 29.1% were graduate students scientific initiation. Qualitative methods were used by 43.8%. Furthermore, 99.2% were classified as Group III thematic area; 58.8% researches were conducted in public institutions and 31.7% enrolled professionals, mostly nurses as research subjects. Informed Consent accounts for 56.4% of the REC's queries. The experience of the REC of the University of São Paulo Nursing School shows its progressive consolidation.

KEY WORDS

Ethics Committees, Research.
Ethics, research.
Nursing.

RESUMO

O objetivo do estudo foi conhecer a experiência do Comitê de Ética em Pesquisa da Escola de Enfermagem da USP (CEP-EEUSP), nos seus primeiros seis anos. O estudo exploratório, descritivo, retrospectivo e de abordagem quantitativa foi realizado pelo levantamento dos registros do CEP-EEUSP e dos 401 protocolos de pesquisa submetidos à apreciação, no período de 31 de agosto de 1998 a 17 de setembro de 2004. Os resultados evidenciaram que 98,7% dos projetos submetidos eram de pesquisadores da EEUSP; 31,4% eram de dissertações de mestrado e 29,1% de iniciação científica. Quanto ao método, 43,8% propunham a utilização do método qualitativo. Além disso, 99,2% dos projetos pertenciam à área temática do Grupo III; 58,8% previam a utilização de instituições públicas e 31,7% tinham profissionais, principalmente enfermeiros, como sujeitos das pesquisas. O Termo de Consentimento Livre e Esclarecido foi responsável por 56,4% das pendências. A experiência do CEP-EEUSP mostra sua progressiva consolidação.

DESCRIPTORES

Comitês de Ética em Pesquisa.
Ética em pesquisa.
Enfermagem.

RESUMEN

El objetivo de este estudio fue conocer la experiencia del Comité de Ética en Investigación de la Escuela de Enfermería de la USP en los primeros seis años de funcionamiento. Se trata de un estudio exploratorio, descriptivo, retrospectivo e de abordaje cuantitativo realizado con base en los registros del CEP-EEUSP y de los 401 protocolos de investigación presentados para evaluación en el período del 31 de agosto de 1998 hasta 17 de septiembre de 2004. Los resultados mostraron que 98,7% de los proyectos fueron presentados por investigadores de la EEUSP; 31,4% eran de trabajos de maestría y 29,1% de iniciación científica. Cuanto a los métodos utilizados, 43,8% de los proyectos eran relativos al abordaje cualitativo. Además, 99,2% pertenecían a la área temática del Grupo III; 58,8% propusieron la utilización de instituciones públicas y 31,7% tenían profesionales, principalmente enfermeros, como sujetos investigados. El Termo de Consentimiento Libre e Informado fue el responsable por 56,4% de las pendencias. La experiencia del CEP-EEUSP muestra su progresiva consolidación.

DESCRIPTORES

Comitês de Ética em Investigación.
Ética em investigación.
Enfermería.

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INTRODUCTION

Historically, Review Boards (RB) are created as a response to the moral implications of the technical-scientific development in the biomedical field, after the discovery of hideous crimes against humanity and the most basic human rights that can be committed in the name of research and scientific progress⁽¹⁾.

The need for the creation of review boards to evaluate research protocols was mentioned in the Declaration of Helsinki⁽²⁾, in the International Ethical Guidelines for Biomedical Research on Human Beings (CIOMS)⁽³⁾ and the Brazilian National Health Council (CNS) Regulation #01/88⁽⁴⁾. With the CNS Resolution 196/96⁽⁵⁾, the creation of RBs was regulated in Brazil, which predicts that every research project involving human beings must be evaluated by a RB before it is executed.

The RB must be made up by a number of members of no less than seven members, including the participations of the healthcare, exact, social and human sciences, and at least one member of society to represent the users. It must have members of both sexes, and no more than half of its members may belong to the same professional category. The composition of each RB must be defined according to the institution's discretion, and at least half of its members must have research experience⁽⁵⁾. It is important for the researchers to incorporate the importance of research ethics, exposing the ethical issues in their projects. Ethical abuses and mishaps will not be entirely avoided by guidelines or documents. Effective ethical controls involve the development of the researchers' sensibility regarding research ethics. Demands for ethical behavior may upset people since it seems overly evident, being therefore an unnecessary point to bring forward. However, ethical considerations do not always receive adequate attention⁽⁶⁾. As such, the RBs offer a new perspective on research projects, making the projects available for the scrutiny of more people in addition to the researchers themselves and their sponsors, when they exist, regarding their compliance with the established guidelines. Resistance, if any, stems from those who believe that ethical competence should always be paired with technical competence⁽⁷⁾. It is worth noting that the submission of projects to the RB should not be viewed as setbacks for the execution of the project, but, on the other hand, to encourage them under the auspices of ethics and the protection of the human beings⁽⁸⁾.

The experience in the RB-EEUSP resulted in this study, whose purpose is to review the activities developed in the beginning of the history of the Review Board, which makes it possible not only to build the history of the RB-EEUSP, but also to visualize its evolution.

OBJECTIVE

General: Reviewing the activities of the Review Board (RB) of the School of Nursing at University of São Paulo since its creation, in August 1998, until September, 2004.

Specific: Describing the composition and the activities of the RB-EEUSP; presenting the number of projects evaluated by the RB-EEUSP; reviewing the researchers' origins; verifying the methods most usually used for research development; identifying the academic purposes of these studies; knowing who are the subjects of the studies and the nature of the institutions where the research would happen; verifying the number of funded projects and the origin of the funding; identifying projects in special areas; reporting the result of the appreciation of projects by the RB-EEUSP and identifying the most incident causes of pending requests.

METHOD

This is an exploratory, descriptive, retrospective and quantitative study. With the authorization of the institution and after being granted permission by the RB-EEUSP to use its documents, the registries from August 31st, 1998 to September 17th, 2004 were retrieved, along with the the 401 research protocols submitted for appreciation during that period.

All the 401 projects submitted during that period were used to analyze the yearly activity of the Committee (number of projects submitted per year) and the origins of the researchers. Since two researchers requested that their projects were removed before their evaluation, 399 projects were effectively evaluated.

In the present study, the characterization of the members of the Committee, both the seat holders and their replacements, totaled 18 members, including professional category, gender and highest academic degree.

The data were collected with an instrument that contained the items deemed necessary to achieve the study objectives and submitted to descriptive statistical analysis, using the software *SPSS for Windows v. 9.0 (Statistical Package for the Social Sciences Inc., Chicago, IL, EUA)*.

RESULTS AND DISCUSSION

From August, 1998 to September, 2004, the composition of the RB-EEUSP complied with the requirements of multidisciplinary, the representation of users and of both genders. The requirement of having 50% of its members with research experience was also complied with by the RB-EEUSP, which had head professors, associate profes-

It is important for the researchers to incorporate the importance of research ethics, exposing the ethical issues in their projects.

sors, doctors and masters among its members. It should be noted that this composition refers to both seat holders and replacement members, which will be referred to as members from now on.

The proposed professional heterogeneity, the representation of both genders and academic degrees, in addition to the representation of the users, aim at a more comprehensive ethical analysis of the protocols. Also, the conditions needed for the exercise of ethics – freedom for discussion, humility to respect the position of another and greatness to alter one's own, in case it is inappropriate⁽⁹⁾. Furthermore, peremptory positions that prevent dialogue or the confluence of different opinions should not be brought forward.

Regarding the yearly distribution of the 401 research projects submitted to the RB-EEUSP in the study period, the first four projects were registered in the Committee in December, 1998, being evaluated only in the meeting held in February in the following year, as they had not been presented in time to be analyzed in the last meeting of the year. They were included among the projects presented in 1991, adding up to 41.

In the following years, an increased number was observed, with some oscillations, in the number of projects. Therefore, 87 projects were submitted in 2000; 84 in 2001; 69 in 2002; 73 in 2003; and, in 2004, 47 projects had been submitted prior to August 31st, deadline for submissions to be evaluated in the September meeting. From the inception of the Committee, in 1998, to August, 2004, 401 projects were submitted.

It should be noted that these figures do not reflect the total number of projects developed by EEUSP researchers in the period, since many of them submit their projects to the RBs of the institutions where they intend to collect data, especially if the study field institution requires it. As such, not all projects are sent to the RB-EEUSP.

All the 401 (100%) projects registered in the Committee were essentially from faculty members and graduate students of the school itself. Outside researchers submitted proposals to the RB-EEUSP when they intended to collect data in the institution. Therefore, 396 (98.7%) projects were from EEUSP researchers and only five (1.3%) were from outside researchers.

The projects effectively evaluated by the RB-EEUSP (n=399) could be rated as follows, after the first evaluation: *approved*; *approved with pending aspects*; *pending approval*; *refused* and *exempt*, which was the case when the project would not involve human beings and therefore not need the Committee's approval. To clarify: projects with pending aspects were classified in *approved with pending aspects* and *pending approval*. *Approved with pending aspects*: When the protocols were pending and the answer to requirements had to be re-evaluated in a RB meeting, and *pending approval*, when the protocols were pending, but

did not need to be re-evaluated by the RB, since the pending aspects in these were minimal, and the reviewer or coordinator of the RB was in charge of verifying such aspects. Therefore, of the 399 projects submitted, 115 (28.8%) were approved; 232 (58.2%) were approved with pending aspects; 41 (10.3%) were pending; five (1.3%) were rejected and six (1.5%) were not applicable to the CNS Resolution 196/96, being considered exempt.

Considering that 11 projects were excluded, five due to rejection and six due to being exempt, 388 projects were assessed.

Regarding the purpose of the project development, the following distribution can be observed among the 388: there were 122 (31.4%) master degree theses, 113 (29.1%) scientific initiation papers, 63 (16.2%) doctorate dissertations, 28 (7.2%) specialization papers, three (0.8%) undergraduate term papers, two (0.5%) from free lecturers and 57 (14.7%) had other purposes.

It is observed that the projects more usually submitted were master degree theses (122), which, when compared to the number of doctorate dissertations (63), amounted to nearly twice as much. One of the justifications could be the ratio between master and doctoral students, since the number of students enrolled in the EEUSP master degree programs is much higher than the number of students enrolled in the doctorate programs. Also, the number of scientific initiation papers (113) should be noted, as it makes the involvement of undergraduate students in research projects evident and reiterates the importance of the discussion about research ethics with them.

Regarding research funding, the field *sponsor* in the submission documents was filled in only 14 (3.6%) of the 388 (100%) protocols; 356 (91.8%) indicated *not applicable*, and 18 (4.6%) left the field blank. Of those who filled in the *sponsor* field, nine of them indicated FAPESP and five indicated CNPq. As such, it was evident that when the evaluated projects were funded, the sponsors were research development agencies, with no other sponsors except for the researchers themselves. It seems that the purpose of requiring this sort of information is to identify possible conflicts of interest that may exist in the project development funding. This concern may be understood by the CONEP analysis of the project sponsors' profiles, which resulted in a large majority (92%) being funded by the pharmaceutical industry⁽¹⁰⁾.

Regarding the theme of the projects, according to orientations in the back of the submission document, certain aspects should be accounted for, such as the risks involved, especially those that *belong to areas with a higher prevalence of ethical issues and little consensus about ethical attitudes*⁽¹¹⁾. Therefore, projects classified as Group I are those that refer to the special themes mentioned in the CNS Resolution 196/96. The special themes related to new drugs, vaccines and diagnostic tests are classified as Group II. All other themes that do not match these two special themes

are classified as Group III. In the RB-EEUSP, of all 388 (100%) projects, 385 (99.2%) were rated as Group III and only three (0.8%) belonged to Group I. Two of these regarded *indigenous populations* and one was *submitted to CONEP by the RB*. These data show that projects evaluated by the RB-EEUSP, mostly, had a low prevalence of risk for the study subjects.

Regarding the research methods, of the 388 (100%) projects, 170 (43.8%) proposed a qualitative method, 144 (37.1%) a quantitative method and 74 (19.1%) a quantitative method, which shows the prevalence of a qualitative approach in the projects submitted. This reality is probably less common in Review Boards, which may be the reason why the ethical aspects of research have been given little attention when compared to the plethora of the biomedical experiments on human beings⁽¹²⁾. Regardless of the method to be used, the ethical principles in research must be preserved in the study design itself, considering the object, the objectives, theoretical references, investigation strategies, publication of the results and the researchers' objectives⁽¹³⁾.

Regarding the types of institutions proposed for the execution of studies, 228 (58.8%) projects were developed in public institutions; 40 (10.3%) in private or philanthropic institutions; 27 (7.0%) in public and private institutions; and 43 (11.1%) had proposals for developing studies in other places, such as low-income communities, indigenous communities, rural communities, public places, patients' households, events, the Internet, among others; in 50 (12.9%) of the projects it was not possible to identify the nature of the institution.

Most of institutions selected as study places correspond to public institutions. The profusion of such institutions for the development of research can be justified due to the comprehensiveness and complexity of the public healthcare system and because they correspond to the highest number of internship fields for students of the School of Nursing at University of São Paulo. As a consequence, students remain closer to their teachers in these fields and are more committed to contributing for the improvement of the healthcare provided in those institutions.

Regarding the study subjects, it is worth noting that the subjects were not mutually exclusive in the studies, and more than one subject category could have been proposed for each project. Of the 388 projects, 123 (31.7%) proposed studies focusing on professionals, with nurses being the ones most commonly observed; 73 (18.8%) focused on patients; 62 (16.0%) focused on students; 38 (9.8%) focused on workers; 31 (8.0%) focused on family members; 31 (8.0%) focused on faculty members; 25 (6.4%) focused on women; 20 (5.2%) focused on medical records; 19 (4.9%) focused on children and adolescents; seven (1.8%) focused on senior citizens; two (0.5%) focused on

indigenous individuals and 12 (3.1%) selected other subjects, such as athletes, residents of a given city, the population in general and representatives of certain segments of society, among others.

When this category was verified individually, it was observed that the *professionals*, who usually seem to present low vulnerability, were privileged in the projects. However, even groups considered less vulnerable, depending on their bonds with the researcher, such as their lack of resources, their necessities and frailties, may become more vulnerable, and must receive special protection regarding their rights and well-being.

Regarding the reasons for pending approval, it is worth noting that several reasons could be identified in the same project, both related to the written term of consent and other pending aspects, which made the number of reasons to exceed the number of pending projects. Inadequacies of the term of consent were the most frequent reasons, among others that were also identified. Therefore, of the 388 projects, 220 (56.4%) had pending aspects related to the term of consent, and 170 (43.6%) studies had other pending aspects. The predominance of reasons for a pending

status related to the written term of consent also occurs in projects submitted to the CONEP and other RBs (11,14-15). It is worth noting that the same project may still have more than one reason for pending status related to the term of consent or other pending aspects.

The data show that the pending aspects regarding the term of consent were due to: *language* in 82 (21.1%) projects, focusing on the necessity of adapting it to make it clearer

for the study participants; *content* in 58 (14.9%) project, focusing on the necessity of adapting it to include the risks and benefits, recording the interview, the study procedures, feedback and publication of results; *form of contacting* the researcher in 49 (12.6%), when not mentioned in the term of consent; *purpose* in 30 (7.7%), due to lack or the incomplete disclosure of the purposes; *rights of the study subjects* in 30 (7.7%), when incomplete or absent; *copy of the term of consent* in 17 (4.4%), when there was no term of consent or when the study would be performed with different subject categories, requiring different terms of consent for each category; *identification of the researchers* in 15 (3.9%), when they were not identified; *the RB-EEUSP's telephone number* in seven (1.8%) projects, when not included; and *the researcher's signature* in four (1.0%), when the term did not have a space for the researcher's signature. Certain items, such as purpose, rights, researchers' identification, form of contacting the researchers and the RB's telephone number could also be considered as part of the item *content*, but it was decided that they would be shown as separate items. It is evident that these difficulties in communication between the researcher and the study generate obstacles for obtaining informed consent.

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Other pending aspects in addition to the term of consent were: *method* in 127 (43.9%); *letter requesting authorization* in 59 (20.4%) projects, when there was no letter from the institution where the data collection would be performed authorizing the study; *project* in 50 (17.3%), when the project needed further clarification about the project or the inclusion of non-contemplated items that hindered the evaluation; *data collection instrument* in 25 (8.7%), when these were not attached or when some type of clarification was necessary; *chronogram* in 19 (6.6%), when considered incompatible; *submission document* in 7 (2.4%), when corrections in this document were deemed necessary; and the researchers *résumé* in 2 (0.7%), when not present.

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FINAL CONSIDERATIONS

The experience of the RB-EEUSP shows its progressive consolidation. The composition met the requirements of multidisciplinary, representation of both genders and research experience. The projects submitted were mostly master degree theses and scientific initiation papers; the studies were funded by research development agencies or by the researchers themselves; the preponderant proposal was the use of qualitative methods; they belonged almost exclusively to the Group III thematic area; requested the use of public institutions, and usually had professionals as the study subjects. The written term of consent was the cause for many pending approvals.