Perception of Medicine and Nursing academics regarding research ethics committee's importance

Juliana Dias Reis Pessalacia
Gustavo Fernandes
Patrícia Maluf Cury

Resumo O estudo objetivou conhecer a percepção dos alunos quanto à importância da bioética, bem como do envio do projeto de pesquisa ao comitê de ética em pesquisa (CEP). O levantamento foi realizado com 19 acadêmicos de Medicina e Enfermagem, que encaminharam projetos de pesquisa ao CEP da Faculdade de Medicina de São José do Rio Preto. Foi realizada uma entrevista com questões fechadas e abertas. Os resultados demonstraram que a principal dificuldade é o entendimento quanto aos documentos necessários e o preenchimento dos formulários, citada por 58% dos alunos; 25% também relataram falta de orientação pelos docentes quanto a esses aspectos. Essas dificuldades geraram sentimentos como ansiedade e preocupação, ante os quais 95% dos alunos ressaltaram a necessidade de inserção da bioética na grade curricular dos cursos de graduação.

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

CEP approval no. 4.039-2003

Juliana Dias Reis Pessalacia Nurse, PhD in Nursing at Ribeirao Preto Nursing School of the University of Sao Paulo (USP), deputy professor at Federal Univesity of Sao Joao Del Rei (UFSJ), Minas Gerais, Brazil

As undergraduate and graduate students' advisors in a public university, as well as members of research ethics committees involving human beings, we experienced academic's anguish at the time of submission of research projects to the committee. These feelings, often, attributed to possible delay in research processing, to lack of knowledge and guidance regarding filling the protocol to be submitted, in addition to doubts and lack of knowledge over ethical aspects related to research involving human beings. Considering the frequency of such situations, interest in knowing academic's perception emerged in regarding CEP performance and role, as well as to check major feelings awaken at the research project submission. However, this study targeted to know the perception of Medicine and Nursing undergraduate courses academics

Gustavo Fernandes
Physician, graduated at the Faculty of Medicine of São José do Rio Preto (Famerp), intern in Surgery at the Basis Hospital of Sao Jose do Rio Preto, Sao Paulo, Brazil

Patrícia Maluf Cury
Pathologist physician, PhD in Medicine at the University of São Paulo (USP), deputy professor and teaching coordinator at tge Faculty of Medicine of Sao Jose do Rio Preto (Famerp), Sao Paulo, Brazil

regarding the importance of bioethics and of submission of research project to the research ethics committee (CEP).

CEP performance

Ethics, as discipline, refers to critical reflection on human behavior, a reflection that interprets, discusses and raises questions, investigates values, moral principles and behaviors searching for the good, of well-being of life and society[1]. Bioethics, in its turn, may be considered as the systematic study of human behavior in the realms of biological and health sciences, while analyzing this behavior in the light of moral values and principles. Hoever, to define it briefly is difficult since definitons tend to set borderlines, and one considers that bioethics should not have them [2].

From the assumption that the ethics task is searching and defining reasons that justify what to do, bioethics is, then, necessarily a multiporofessional reflection, related to the several fields working in health [1]. Literature records that the expression 'bioethics' was created and set under circulation in 1971, by the American oncologist, Van R. Potter. The title of his book– *Bioethics, bridge to the future* – refers to a new discipline that, briefly, it is possible to say that it should allow bridging to a better quality of life. Nevertheless, the expression, in its fast dissemination, acquired the specific and scientific meaning of *a new dimension of research in the realm of academic studies*, emerging, in less than a decade, as an autonomous discipline. It began, in restrict conception, to nominate ethics problems generated by advances in medical and biological sciences[3].

CEP are multidisciplinary collegiate that review research projects to evaluate if integrity and rights of those participating in research were insured[4]. Regarding their origin, it is admitted that they emerged with the discovery

of the renal dialysis machines, which brought major ethical questioning: as there are four fold more renal patients than the capacity of machines, who should get priority to enter the dialysis program? Physicians from Seattle, aiming at answering this question, resorted to local medical association and a lay committee comprised to decide which patients should be benefited[5].

At the time of Resolution 196/96 elaboration by the National Health Council (CNS), the idea that CEPs should be established in order to favor provision of points of view from all involved was consolidated. Also, to allow inclusion of diverse interests, either from researchers, sponsors, research subjects or from community[6], in order to reproduce the pluralist spirit and participative structure that governs the establishment of CNS itself and State and Municipal health councils. CEPs, thus, should comprise professionals from human, exact, and social sciences areas, and community representatives [7].

The resolution foresees that every institution undertaking researches involving human beings should have a CEP. Such committee comprises of an interdisciplinary and independent collegiate, with public duty, targeting protection of research subjects interests in their integrity and dignity, as well as toward development of research under ethical standards. It is worth mentioning that CEP should perform also educational role, promoting discussion with seminars or other ways that enable reflection and to discuss ethics topics, and on the difficulties in submission process of a research protocol [7].

Many points should be weighted at elaboration of a research project, involving legal, moral, and ethical aspects. When human beings participate in researches, the four basic bioethical principles should be preserved always, as stated by the principialist model: respect for the individual (autonomy), beneficence (including non-maleficence), and justice. Mentioned resolution on ethics and research described such principles, and they should be taken into account as basis of CEP members decisions [8].

One searches to guarantee the principle of autonomy with the free and clarified consent term (TCLE) – a document that formally assures informed consent in Brazil. This procedure, derived from Anglo-American legislation, pins the individual as owner of his body, capable to accept or to reject treatment that could save his life. Basic assumption is that every human being has the right to determine what to do *for* or *with* his own body. Patient (or research participant) must have full knowledge of the prognostic, complications, consequences, disconfort, costs, inconveniences, risks, and experiences[9].

The principle of *beneficence* includes moral obligation to act in benefit of the other [10]. The Belmont Report, disclosed in the United States of America (USA) in 1978, did not

distinguish between *beneficence* and *non-male ficence*, considering that to provide benefit and non-maleficence seems almost trivial when dealing with health procedures and practices. However, Beauchamp and Childress, original authors of principlist model, claim differences for such principles by stating that obligations of not jeopardizing others are clearly different from helping others. It is worth highlighting, still, the principle of *justice*, regarding adoption of norms assuring equitable distribution of benefits, risks, and costs [11].

Concerning the measures to protect individuals, one stands out the importance of anonymity and privacy, mentioned the difference between them. In anonymity, researcher is incapable to establish a connection between data and the individual to which they refer; in privacy, although connection between both can be set, the researcher assumes the commitment of not disclosing those[12].

Method

It is a descriptive and exploratory study, undertaken from a randomized sample with 19 academics from undergraduate courses in Medicine and Nursing, who had submitted research projects to CEP at the Faculty of Medicine of São Jose do Rio Preto (Famerp). Data were requested from CEP related to names and series of all academics who submitted projects during previous year of the study, amounting to 43 research projects. Out of this total, 10 academics were drawn from Nursing and Medical Schools, respectively. However, during the study, one academic from Medicine gave due to unavailability of time. Therefore, 10 (53%) of drawn academics were taking Nursing undergraduate courses and 9 (47%) were in Medicine.

The study conducted at the Faculty of Medicine of Sao Jose do Rio Preto/SP, state autarchy that shelters two undergraduate courses: Medicine and Nursing. It is an institution targeted to teaching and research, and it has a research ethics committee since 1997. The committee, of advisory nature, gathers its members monthly, and it receives a large amount of research coming from faculty's academics, under responsibility of their professors. The average monthly demand of submitted research projects is of 45 projects.

Data collection instrument was a semi-structured interview with closed and open questions related to academics' perception regarding submission of research project at CEP, along with major feelings developed from lived experience. In the interview, students were identified numerically, thus, keeping privacy and anonymity. Data were grouped manually, categorized according to pertinence, and listed according to the objectives of the study. It presented as percentage figures and in a descriptive way, with discussions of implications for the academic training. Some of the academics' speeches were available, aiming at illustrating experiences and perceptions presented by the later.

Results and discussion

In the first questions, about difficulties in preparing a project to be submitted to CEP, six (32%) students reported not having difficulties with the procedure, and 13 (68%) stated having some difficulties. Out of these, considering that a student could present more than one difficulty, 11 (58%) had difficulties in filling the forms presented in the protocol, 3 (16%) related to authorizations and signatures, 3 (16%) with deadlines (dates) for project submission to CEP, and two (10%) with preparation of the finance budget to be submitted. In this respect, the following speeches stand out:

Ac 16: "There should be simpler forms (...) *they are too long"*;

Ac 10: "The supervisors themselves do not know the forms and types of projects that could be or could not be submitted to CEP";

Ac 18: "It is a bureaucracy. Before submission, one has to go to several sectors requesting authorization";

Ac 12: "The project returned several times as there was always lacking a document".

The results show that major difficulty of Medical and Nursing academics is to understand which are effectively the documents for projects submission, as well as filling up research protocol forms to be sent CEP. Analysis undertaken by the National Research Ethics Commission (Conep), from January to July 1998, regarding major pendencies of submitted projects to the CEP/Conep system, it was found that around 63% were due to incomplete protocols [6].

Regarding adequacy to protocol structure, it can be defined as a set of documents that researcher prepares as part of the elaboration process of his research project. It is worth emphasizing that this preparation has a bureaucratic dimension, which tends to cause a certain amount of unhappiness to researcher, who feels to be losing a valuable time gathering documents that, at first glance, do not seem to have greater relevance. This bureaucracy, however, has its legitimacy when kept within due limits and at the service of scientificity and ethnicity of the research project [13].

However, literature shows that is not document processing, filling forms or the existence of hierarchy, foreseen for committees functioning that can categorize them as a merely bureaucratic instance, nor would had been these characteristics, isolated, the more concerning issues. The major problem is the way of the relationships set between committee members and the system that they represent[14].

At the interview second stage, dealing with feelings involved in the submission process of a research to CEP, the following were mentioned, considering that every academic could report more than one: anxiety 5 (25%),

worry 4 (21%), tranquility 4 (21%), insecurity and fear 3 (16%), despair 1 (5%), anger 1 (5%) and joy 1 (5%). Next, the most representative speeches related to this point:

Ac 14: "I understood that it was part of the process, it was one more stage of the work";

Ac 11: "Anguish, because I did not know how to fill in and got into despair";

Ac 1: "I was at easy as I had prepared the project well before the meeting";

Ac 3: "I was worried, fearing not been approved; after non-approval I got angry";

Ac 7: "Insecure, because I did not have ever done a work; I did not have knowledge. I wanted to show to someone, but the professor did not help".

The hardships found by academics to submit a research project to CEP may generate feelings with anxiety and concerning, mainly related to waiting approval. However, one may note in speeches that when students are previously guided by teachers in preparing the material, they are more self-confident and at easy with the submission process, as one can see in *Ac 1*. One should emphasize that protocol submission to CEP is the responsibility of qualified professional in the subject area of the work, that is, the supervisor and not the student.

The third question tried to identify students' knowledge which ethics aspects are discussed and evaluated by CEP members. Considering that each participant could quote more than one, the following were mentioned: research losses 13 (68%), methodology 9 (47%), objectives 4 (21%), secrecy 2 (10%), relevance 2 (10%), free and clarified consent term 1 (5%) and other aspects 1 (5%). The following speeches stand out:

Ac 5: "If methodology offers condition to execute work";

Ac 3: "If research will not cause physical or moral harm to the individual";

Ac 4: "If one will not jeopardize the institution where one will interview".

Concerning academics' perception regarding aspects of their projects evaluated by CEP members, one notes that despite difficulties in preparing documentation and the dimension of their importance, they are able to perceive which ethical aspects will be evaluated, while evaluation of research risk is mentioned most, that is, if research could bring some kind of harm to participants.

According to CNS Resolution 196/96, research ethnicity implies in: 1) free and clarified consent of participants and protection of vulnerable groups and those legally incapable (autonomy). In this sense, research involving human beings should be

treated in their dignity, respect them in their autonomy and to protect them in their vulnerability; 2) pondering risks and benefits, both current and potential, individual or collective (beneficence), committing benefits to the most and minimum damages and risks; 3) guarantee that foreseeable damages will be avoided (non maleficence); 4) social relevance of the research, with significant advantages for research subjects and minimization of onus for vulnerable subjects, which ensures equal consideration of involved interests, not losing the sense of its sociohumanitarian destination (justice and equity)[15].

Data show that 100% (19) of interviewed emphasized CEP importance related to research projects evaluation, as pointed by phrases:

Ac 1: "I believe to be very important because someone has to evaluate if researchers are coercing or exposing people";

Ac 19: "Sometimes one is anxious to undertake the research and forgets to respect the human being, it is crucial that research to be seen with other eyes";

Ac 18: "If there is not any restriction, unintentionally one may cause a moral or physical harm to the other individual".

Such perception meets Resolution 196/96, stressing that CEP were established to defend research subject interests in their integrity and dignity and to contribute for the development of research within ethical standards[16].

Regarding guidance gotten by academics, 14 (75%) reported professors' due guidance both in research project preparation and their submission process to CEP. However, 5 (25%) mentioned that such guidance fell short of needed. The following speeches reflect these two antagonic situations:

Ac 9: "I think that I got more support than all my colleagues. I filled forms and she corrected them, clarifying my doubts";

Ac 10: "No, supervisors had little knowledge regarding filling the forms, as well as on CEP importance".

Therefore, one notes that large portion of difficulties found by academics relates to lack of guidance by teachers in submission process. Thus, it stands out the necessity of schools to be concerned and to incorporate attitudes and morally suitable behaviors that society expects from the professional, particularly the social commitment. Academics have the right to competent and dedicated professors [17] and with specific formation and training [18].

Concerning the issue about needed bioethical learning in undergraduate studies, specifically about research ethics, 18 (95%) students stated that did not have enough learning and only 1 among them (5 %) replied that curriculum grid already encompass mentioned content:

Ac 3: "This issue is little approached, we don't have even a discipline approaching this, and it would be very interesting";

Ac 10: "It is insufficient while course load, the quality of content is bad, since professors themselves who teach scientific methodology show that they do not have knowledge about the subject";

Ac 17: "Only those who do scientific works and have interest, get the information";

Ac 16: "Yes, it is sufficient in the Preventive Medicine discipline. Whoever does research has to run after more knowledge about research ethics".

Students proposed, in the last question, what they thought to be the best for bioethics teaching: 12 (63%) stressed the importance of inserting the content in courses curriculum grid; 4 (21%) suggested the approach in extension courses; 2 (10%) suggested approaching in preexisting discipline, and 2 (10%) stated the need of a specific discipline for bioethics, considering that each student could provide more than one suggestion.

Ac 16: "Ethics is innate with the person, one cannot teach someone to be ethics";

Ac 19: "It is important that extension courses should exist, but just for students interested in undertaking researches";

Ac 9: "There should have bioethics classes, and incentive to scientific works undertaking within curriculum grid right in the beginning of undergraduate courses";

Ac 18: "Bioethics League project should - continue if possible to establish a bioethics discipline in the faculty".

One of the goals to introduce bioethics as basic discipline at universities is to provide foundations so future professionals can solve moral and ethical problems in their working practice[19], preparing the individual to serve with responsibility, competence and humanism those who subordinate, consciously or not, of acts that will be undertaking. Universities, conscious of their responsibilities in forming woman and mend, should stimulate environment that proportionate substantive moral formation to their students[20]. Students should be prepared, starting at undergraduate courses, to assume with responsibility their social role, both in professional and personal dimensions, since they are, in their turn, opinion makers who could arrive at influencing irrestrictly the fate of the nation.

Final considerations

Despite reported experiences reflect academic's difficulties in the submission process of research protocols to CEP, it is worth highlighting that these difficulties, often, are described also by the responsible researchers themselves (professionals or professors). Our experience, while CEP members, confirms also such conflict. We noticed, in contact with professionals who submitted for the first time research projects to CEP (and experienced these difficulties) perceptions and similar reactions

to similar reactions of interviewed academics.

From reports, we could realize that CEP role should be rethought, since it is noticed that an approach targeted to more than systematic checking of bureaucratic requirements compliance toward discussing ethics or moral procedures features. And despite existence of computerized system for document processing, the National Information System on Research Ethics involving Human Beings (Sisnep), many CEPs still adopt bureaucratic ways for protocol submission, adding new forms to those already existing in the system.

Thus, it stands out the importance of greater reflection regarding CEP performance in as much as instances targeted to assure compliance to ethics requirements, and not merely bureaucratic ones. In addition, it stresses the importance of committees' educational function, mainly in educational institutions, to clarify researchers regarding procedures involved in research protocols and of ethical features in researches with human beings.

Resumen

Opinión de los académicos de la Medicina y Enfermería en lo referente a la importancia del comité de ética en la investigación

El objetivo del estudio era saber la opinión de los alumnos en lo que atañe a la importancia de la bioética y sobre el envio del proyecto de la investigación al comité de ética en pesquisa (CEP). El estudio fue realizado con 19 académicos de Medicina y Enfermería, que habían dirigido proyectos de investigación al CEP de la *Faculdade de Medicina* (Universidad de Medicina) de São José do Rio Preto. Fue realizada una entrevista con preguntas cerradas y abiertas. Los resultados demostraron que la dificultad principal es el acuerdo en lo referente a los documentos necesarios y el rellenado de los formularios, citado por 58% de los alumnos; el 25% de éstos relataron que hay una carencia de orientación por los profesores en lo que se refiere a estos aspectos. Estas dificultades generaron sensaciones como ansiedad y preocupación y el 95% de los pupilos habían dicho que hay una necesidad de inserción de la bioética en los cursos de graduación.

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

Abstract

Perception of Medicine and Nursing academics regarding the importance of research ethics committee

The objective of the study was to access students' perceptions the regarding bioethics importance and the necessity of submitting research projects to research ethic committee (REC). The study performed with 19 academics at the *Faculty of Medicine of Sao Jose do Rio Preto,* who attended Medicine and Nursing courses, and submitted research projects to PEC. Interviews included closed and opened questions. The results showed that main difficulties are the agreement regarding the needed documents and filling forms, mentioned by 58% of students; 25% also expressed lack of professors' guidance regarding such aspects. These difficulties generated feelings like anxiety and concern, and 95% of students mentioned the need of introducing bioethics in undergraduated courses curricula.

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

References

1. Pessini CPBL. Bioética: alguns desafios. 2ª ed. São Paulo: Loyola; 2002.
2. Gottschall CAM. Do mito ao pensamento científico. São Paulo: Atheneu; 2003.
3. Barboza HH. Princípios da bioética e do biodireito. Bioética 2000;8(2):209-16.
4. Wood GL, Haber J. Pesquisa em enfermagem: métodos, avaliação crítica e utilização. 4ª ed. Rio de Janeiro: Guanabara Koogan; 2001.
5. Fernandes Jr H. Bioética e comissões nacionais no estado brasileiro [Dissertação]. Brasília, DF: Universidade de Brasília-UnB;2002.
6. Freitas CB, Hossne WS. Pesquisa com seres humanos. In: Costa SIF, Oselka G, Garrafa V, organizadores. Iniciação à bioética. Brasília: Conselho Federal de Medicina; 1998. p.193-205.
7. Schnaider TB. Ética e pesquisa. Acta Cir Bras 2008;23(1): 107-11.
8. Francisconi CFM, Goldim JR. Ética aplicada à pesquisa. Cad Ética Pesq 2002;5(9): 8-9.
9. Carvalho MDB, Coelho LC, Pelloso SM. Um aspecto da bioética e do consentimento informado. Revista Universidade e Sociedade 1997;12(16): 24-5.
10. Lolas F. Bioética: o que é, como se faz. São Paulo: Loyola; 2001.
11. Beauchamp TL, Childress JF. Princípios de ética biomédica. São Paulo: Loyola; 2002.
12. Padilha MICS. Questões éticas: cuidados metodológicos na pesquisa de enfermagem. Texto & Contexto Enferm 1995;4(2): 118-32.
13. Martin LM. O protocolo de pesquisa. Cad Ética Pesq 2002;5(10): 25-7.

14. Tomanik EA. A ética e os comitês de ética em pesquisa com seres humanos. Psicol Estud 2008;13(2): 395-404.
15. Fontinele Jr K. Pesquisa em saúde: ética, bioética e legislação. Goiânia: AB; 2003.
16. Hossne WS. Consentimento: livre e esclarecido. Cad Ética Pesq 2002;5(10):3.
17. Kipper DJ, Loch JA. Questionamentos éticos relativos à graduação e à residência médica. Bioética 2002;10(2):107-28.
18. d`Ávila RL. É possível ensinar ética médica em um curso formal curricular? Bioética 2002;10(1):115-26.
19. Gabrielli JMW. Algumas considerações sobre bioética e implicações para a prática clínica. Rev Cent Univ Barão Mauá 2001;1(1):29-32.
20. Urban CA. Bioética clínica. Rio de Janeiro: Revinter; 2003.

Received: 2.8.2010 Approved: 3.15.2010 Final approval: 3.18.2010

Contacts

Juliana Dias Reis Pessalacia – *juliana@pessalacia.com.br*
Gustavo Fernandes – *gusfamerp@uol.com.br*
Patrícia Maluf Cury – *pmcury@famerp.br*

Juliana Dias Reis Pessalacia – Rua São Paulo, 1.037, aptº 104. Santo Antônio CEP 35502-025. Divinópolis/MG, Brasil.