Globethics Repository



Research protocol

This page was generated automatically upon download from the Globethics Repository. More information on Globethics see https://www.globethics.net. Data and content policy of Globethics Repository see https://repository.globethics.net/pages/policy.

Item Type	Article
Authors	Lee dos Santos, Mary;Imbroisi Valle Errera, Flávia
Publisher	Conselho Federal de Medicina
Rights	Creative Commons Copyright (CC 2.5)
Download date	2026-11-07 13:55:12
Link to Item	http://hdl.handle.net/20.500.12424/236968

Research protocol: the challenge of ethical improvement

Mary Lee dos Santos
Flávia Imbroisi Valle Errera
Roger Bongestab
Elisardo Corral Vasquez

Resumo O trabalho analisa protocolos de pesquisas no âmbito universitário submetidos nos últimos três anos ao Comitê de Ética em Pesquisa da Escola Superior de Ciências da Santa Casa de Misericórdia de Vitória (CEP/Emescam). Este CEP avalia 200 projetos/ano. Os dados foram restritos ao título dos projetos e número de sujeitos. Os achados foram agrupados conforme a Biblioteca Virtual de Saúde (BVS). As pesquisas concentram-se nas categorias saúde do trabalhador; aleitamento materno, saúde materna e da mulher; adolescência, criança e idoso. Economia, indicadores de saúde, alta complexidade e ciência e tecnologia estão ausentes. Considerando que a preferência pela área temática advém da familiaridade com o tema, os dados levantados foram comparados com a experiência dos pesquisadores, registrada na Plataforma Lattes. Sabe-se que hoje as pesquisas são resultado dos esforços passados dos pesquisadores e conhecer o cenário atual da pesquisa acadêmica é importante para planejar o futuro da pesquisa em saúde no país.

Palavras-chave: Bioética. Comitê de ética em pesquisa. Sujeito de pesquisa.



Mary Lee dos Santos
Physiotherapist, Ethics specialist, Master's degree in Collective Health, working in her PhD in Bioethics, Applied Ethics, and Collective Health, university professor, deputy- coordinator of the Research with Human Beings Ethics Committee at Science Higher School of Vitória Holy House of Mercy (CEP/ Emescam), Espirito Santo, Brazil

During academic formation, future health professionals are Introduced to technical-scientific knowledge, to historical evolution of ethical thought, to clinical situations susceptible to multiple approaches, and to those for which there is established ethics and legal consensus [1]. This broad approach assures sound ethics base formation. It is from this global knowledge, reinforce by individual's moral heritage, that decisions in the professional practice on micro location and/or resource allocation, selection of candidates for hospital beds, for intensive care services, high technology or destination of transplant organs originate. In summary, these are bioethical dilemmas that determine access to health services at individual and collective levels [2].

Daily routine at universities show that students are ready to learn what is correct, and he assimilates easierly theoretical



Flávia Imbroisi Valle Errera
Biologist, PhD in Science, Human Genetics working area, university professor, member of Research with Human Beings Ethics Committee at the Science Higher School of Vitoria Holy House of Mercy (CEP/ Emescam), Espirito Santo, Brazil



Roger Bongestab
Physician, internship in General Surgery, graduate studies in Nutritional Therapy, works as physician at intensive care unit, member of the Research with Human Beings Ethics Committee at the Science Higher School of Vitoria Holy House of Mercy (CEP/Emescam), Espírito Santo, Brasil



Elisardo Corral Vasquez
Biophysician, *post doc*, work area in Hypertension, university professor and coordinator of the Research with Human Beings Ethics Committee at the Science Higher School of Vitoria Holy House of Mercy (CEP/ Emescam), Espirito Santo, Brazil

structure of disciplines when he realizes its applicability through good decision. In this environment, the professor deeply influences the learning process. Thus, the professional associated to clinical area transmits credibility in practical knowledge, which is greatest value in transmission of ethics reasoning. In the other hand, professors in clinical area, in influent positions and who do not respect their patients, harm students' ethics formation [3].

It is worth emphasizing the monitor figure – usually a student of more advanced level – who, although constantly following students under his tutelage, does not replace the presence of the head of the discipline and, often, his performance can reinforce primary and ineffective ethical behaviors. It is a commonplace that students approach ethical issues informally and even ludicrously. Usually, monitors, who feel equally uncomfortable in face of such situations, do not reprimand them. Consequently, it is in academic research practice, legal requirement for getting higher education certificate in Brazil, that relationship between students and professors/supervisors/monitors and patient, in majority of cases changed into research subject[4], due to closeness and greater availability, face their greatest ethical challenges [5].

Research at university has the potential to disclose the paths that research will be undertaken in Brazil during the next decades, both in clinical practice and in teaching, by current students when, in their turn, take up managing positions in teaching and health care in the country. Learned or taught ethical concepts, normally, during the first semesters in health sector courses are questioned more vigorously during undertaking of these researches. Such concepts become research with human beings ethics committees (CEP) requirements when disclosing risk *versus* benefit relation publicly, as well as conflicts of

interest, in addition to establish clear methodological limits based in evidences for proposed study. In this scenario, noncomformity reports – from researchers, both students and professors – with CEPs practices are a routine, which, in their turn, are regulated by CNS Resolution 196/96 that defines research in Brazil [6].

Although commendable and necessary, stimulus for research within academic scope faces own difficulties, clearly defined by Queiroz[7] et all as a gap among teaching, research and production activities. An insufficient correspondence between yielded results and society demand regarding prevalent health problems; excessive regional concentration of research groups and of graduate systems; and low applicability of research outcomes, either by its incorporation in government policies and in health services or in industry realm.

Since health public policies designers, as well as those responsible for outlining academic activities in formation, research and extension, aim at fostering national research in the area, it is basic to know paths and profile of studies that are drawn from academic activities. If academia reflects current society and not only a part of it – becoming lesser elitist and more accessible -, it is expected that social hopes and needs manifest in undertaken projects of study. Protocols include investigations made by students with scientific initiation, undergraduate and graduate completion works, in addition to those developed by independent researchers/professors. Even though this investigation shows methodological and ethical complexity, which is the outstanding feature of clinical researches undertaken in Brazil and abroad, it is subjected to the same legislation when dealing with research voluntaries and it must comply equally with scientific rigor.

Objectives

The major objective of current work was to point solutions for CEP functional enhancement, by the assessment of projects profile submitted to the committee during three years, from academic research protocol. The research contemplated also secondary pedagogical character, aiming at contributing with its findings in ethical and scientific formation of academic community of the higher education institution in health sector where mentioned CEP works.

Method and outcomes

This work undertaken from research projects records that were submitted to CEP of the Science Higher School of Vitoria Holy House of Mercy, private institution with philanthropic character, established in March 1968. Targeted to higher education in health sector, it counts with around 1,900 enrolled students and 250 professors.

CEP/Emescam was set in June 2005 and renewed in April 2008. Currently, it comprises 22 members, distributed in equal quantity regarding gender. Concerning area of training, ten of them are physicians, one is biophysician, two biologist, one nutritionist, one chemist-pharmacist, one physiotherapist, one nurse, one pedagogue, one extension representative, one preacher, and two users' representatives. In terms of monthly analyzed projects, it is second in the State and traditionally it receives for evaluation, in addition to projects submitted by researchers from the institution itself, as well projects coming from other educational and assistance institutions that do not have institutional CEP, as well as from autonomous researchers.

Routine consultation to Health Virtual Library (BVS)[8], which in its own, could contribute to steering researched topics, due to higher or lesser easiness to access needed information for research, and as a source of popular reference among health sector students. Table 1 shows protocol distribution, in percentage, of evaluated projects by concentration area, based in BVS adopted classification. All information presented hereto was gotten out of the front sheet that follows each of submitted projects.

Table 1. Classification of researched topics based in BVS criteria

Topics	>10%	10%-5%	<5%	Not any project
Worker's health	12%			
Neurology	11%			
Breast-feeding, and maternal and woman's health		10%		
Elderly health		9%		
Adolescence and child		8%		
Cardiovascular risk and arterial hypertension		7%		
STD and Aids, sexuality		7%		
Public health		5%		
Nursing			4%	
Nutrition			4%	
Endocrinology			4%	
Mental health			3%	
Trauma, ortho and phisiotherapy resources			3%	
Cancer control			2%	

Continued

Continued Table 1

Other*			2%	
Infectious parasitarian diseases			2%	
PO Surgery			1%	
Athlete Health			1%	
Dermatology			1%	
Intensive care			1%	
Asthma and pneumopathies			1%	
Toxicology			0.7%	
Humanization			0.7 %	
Legal medicine			0.7%	
Supplemental health care			0.3%	
Nephrology			0.3%	
Basic health care				x
Health economics				x
Health indicators				x
High complexity				x
Science and technology				x
Social participation and control				x
Health surveillance				x

*Other: evaluation studies of service and other non-classified topics in BVS.

During the period of study, comprising 2005 to 2008, 502 projects were submitted to CEP (yearly average of 200 protocols), of which 70% represent own educational institution researches. In this group, 60% are undergraduates' and scientific initiation courses completion works, 20% graduate courses and 10% are researches without student participation. The majority of studies (90%) are classified as group III (outside special topic area) according to the National Research Ethics Commission (Conep); 60% are prospective kind, and 30% retrospective.

Regarding the number of involved subjects, records show a forecast participation of 64,746 individuals (yearly average of 25,000 research volunteers), of which 15,141 (23%) were included in the special groups, as defined by October/99 version of the front sheet of the standard form for registration of research in the National Information System on Research with Human Beings Ethics (Sisnep), namely: less than 18 years old; mental disabled; embryo/foetus; individuals submitted to

dependence relationship (vulnerability), such as students, military personnel, prisoners; and other conditions in which indigenous communities and ethnical minorities are classified, disease carriers and residents in long permanence institutions vulnerable groups.

The social impact of number of studied subjects in research projects submitted to the committee during that period is understood better, when this total is compared to demographic data, which reveal that 73% of Brazilian municipalities have up to 20,000 inhabitants, according to the Brazilian Institute of Geography and Statistics (IBGE) [9]. It is important to draw such parallel because it shows the scope of CEP/Emescam work, allowing inferring that it derived also from CEP/Conep system dimension. In case of the CEP analyzed in this work, the estimated number of participants in evaluated research projects corresponds to approximately the population of a municipality, just in number of voluntaries coming from the *vulnerable population*. It should be added that research subjects, in their majority, are users of the Unified Health System (SUS).

It was considered as equally relevant researchers' familiarity with the approached topic in research, trying to understand difficulties found in presenting academic studies projects are related to mastering of researched topic. Therefore, it was analyzed also coherence of project with proposing researcher's training and working area.

Public records, in institution's site, of approved projects in 2008 were taken as baseline, and after analysis of data frequency related to responsible researcher training and scientific production.

Discussion

It was found that 78% of researchers-supervisors concentrated work in their own training or working area, effectively characterizing greater mastering in research-approached topic. This result becomes more significant when one notes that among remnant researchers, 12%, although they did not registered scientific production, they have training in researched area. It can conclude that difficulties faced by researchers in submission of projects to CEP do not derive from lack of knowledge of dealt topic.

Among detected causes for non-approval (non-approval or pendency) are technical inadequacies (wrongly filling the front leaf available at Ministry of Health site), which correspond to 40% of the non-approvals. Forwarding mistakes (project unsuitable classification, for example, use of specific forward form for *retrospective* project for submission *prospective* studies and/or vice-versa) represented 20%. Other reasons comprise still insufficient theoretical basis (20%); inappropriate methodology (30%); errors (or doubts) in schedule (40%) and need to adequate free and clarified consent term (TCLE), corresponding to 80% of non-approvals.

Methodological inadequacy corresponds to approximately 30% of non-approval and tendencies reasons of submitted projects. It is well-known enhancement need, mainly in trial outlines in majority of academic research protocols. This becomes significant in sample selection and computation, which is crucial parameters in ethic evaluation of proposed study, since they related directly to research voluntary's performance.

This situation may be justified by little experience of the academic community, particularly in private higher education institutions, which do not work in research traditionally. The scenario aggravated from understanding that academic training should be followed by scientific research, while the later, inclusively, one of the criteria that influences most higher education institution evaluation by the Ministry of Education (MEC). Consequently, CEPs began to receive a greater volume of projects and to serve a large number of researchers from the most diverse areas. As members of CEP/Emescam, and evaluators of products generated by this demand, we consider that a major part of presented projects to meet the requirement for the course completion works (TCC), required by MEC, than innate scientific motivation itself, toward knowledge production in health sector.

Considerable share of projects, around 30% Do not meet pendencies reported in opinions based in the set 60 days deadline. Thus, an opinion survey was undertaken among those responsible for such studies, on the reasons for their default in CEP. This supplementary study showed two of the most frequent justifications for this condition. The first of them deals with students giving up in continue the project, deriving, often, from lack of time to initiate and to conclude research within deadlines established by different disciplines. The second reason mentioned, related to this, refers to the difficulty in complying with deadlines, showing, also, researchers' little familiarity with CEP routine and time schedule to comply with pendencies.

Considering the outcomes found in analysis of the two first variables, the fact that researchers are acquainted with the area in which present project to CEP and the major cause for their non-approval, one may deduce that majority of administrative errors occurs due to lack of information and, eventually, reading CNS Resolution 196/96 [6]. Despite publication of norms and forms, as well as how to fill up needed documentation in institution's site, errors are common, leading to extension of deadline for submission, which, sometimes, constitutes a constraint for project undertaking and, therefore, implies the need for responsible researcher to change originally proposed timetable.

Final considerations

To minimize problems mentioned in this research, CEP undertakes dissemination activities in institution's several departments and courses at regular intervals. Dissemination of criteria set by CNS Resolution 196/96, related to the several stages needed to undertake research projects and in presentation necessary documentation for their submission, is the goal for these educational activities regularly promoted by CEP/Emescam. Such activities are undertaken jointly with the Coordination of Course Completion Works (CTCC), and they involve undergraduate and graduate courses, Methodology of Scientific Research disciplines and correlates, as well as research projects and extension. Constant renewal of students and the requirement to undertake works, however, impose endless demand of continued educational activities, which CEP hardly has the condition to match.

Despite CNS Resolution 196/96 presents a basic script to follow by domestic researchers, research findings allow to infer that researchers do not always understand these information. The committee plans, considering this and the necessity to disseminate and to inform effectively the requirements, timetable, and CEP/Emescam work process, to change its model of funded opinion, showing which item of Resolution 196/96 refers to each point of its analysis.

This measure is an attempt – didactic – to guide authors of research project on minimum ethics requirement to approve their studies and, at the same time, getting academic community closer to ideal conditions, set in terms of the resolution.

One expects that, with this measure, to sediment research at the university in terms of CNS Resolution 196/96, and to propitiate a responsible discussion about use of human beings as research volunteers, excluding *plastered* arguments that *ethical analysis jeopardizes research*[10]. Therefore, it is necessary that all involved, researchers, CEP members, volunteers, patients' associations, professors, students and institutions, are familiarized with the Brazilian norms, lining, routinely and consciously, their studies proposals within the rules that they set. Thus, from their individual experiences, built over a common basis, they can contribute to build a collective, scientific, and ethical knowledge effectively, with deep social relevance.

The outcome of analysis in current study undertaken by CEP/Emescam reveals the necessity and opportunity of CEP of academic institutions to systematically evaluate their behavior and results, aiming at strengthening CEP/Conep system and, mostly, to protect volunteers in health area. The educational measure to be implemented by CEP/Emescam in the model of opinion, presented in this article, is an example of direct application of such studies, which can

contribute – effectively – to improve the mechanism of research ethical control in Brazil.

Resumen

Protocolos de investigación: el desafío del perfeccionamiento ético

El documento analiza los temas y asuntos de la investigación en la universidad en los últimos tres años enviados al *Comitê de Ética em Pesquisa* (Comité de Ética en Investigaciones) de la Escola Superior de Ciências da Santa Casa de Misericórdia de Vitória (CEP/Emescam). El CEP evalúa 200 proyectos por año. Los datos se limitan al título y el número de voluntarios. Los resultados fueron agrupados de acuerdo a la *Bibliotéca Virtual em Saúde* (Biblioteca Virtual en Salud). Los estudios se centran en las categorías salud ocupacional; la lactancia de salud materna, los adolescentes y la salud infantil y de adultos. Economía, indicadores de salud, alta complejidad y ciencia y tecnología están ausentes. La elección de la materia puede ser debida a la familiaridad, por lo tanto se hizo comparación con la experiencia previa de los investigadores, registrados en la Plataforma Lattes. La investigación de hoy es el resultado de esfuerzos anteriores de los investigadores. Conocer la investigación académica es importante para planificar el futuro de la investigación en salud en el país.

Palabras-clave: Bioética. Comité de ética en investigación. Sujetos de investigación

Abstract

Research protocol: the challenge of ethical improvement

The investigation analyzes research protocols at the academic sphere submitted, during the last three years, to the Research Ethics Committee at the Higher School of Science from Vitória Holy Mercy House (CEP/Emescam). This CEP evaluates 200 projects yearly. Title of projects and number of individuals restricted data. BVS model (Health Virtual Library) organized findings accordingly. The researches concentrated in the categories: worker´s health, breast-feeding, maternal and women´s health, adolescents, children and elders. Economy, health indicators, high complexity, science, and technology are absent. Considering that preferred thematic area derives from familiarity with topic, the collected data were compared to researchers' experience,

registered at Lattes' Plataform. It´s known that researches, currently, result from researchers' combined past efforts, and, thus, it is important to know current academic research scenario to plan future health research in the country.

Key words: Bioethics. Research ethics committee. Research subjects.

References

1. Bauman SM. Clinical ethics: what's law got to do with it? Arch Fam Med 1999; 8(4):345-6.
2. Sauwen RF. Direito in vitro: da bioética ao direito. 2ª ed. Rio de Janeiro: Lumen Juris; 2000.
3. Singer PA, Pellegrino ED, Siegler M. Clinical ethics revisited. BMC Medical Ethics [online] 2001 [acesso 16 Abr 2010];2: 1. Disponível: http://www.biomedcentral.com/1472-6939/2/1.
4. Slawka S. O termo de consentimento livre e esclarecido e a pesquisa em seres humanos na área de saúde: uma revisão crítica. [Dissertação] São Paulo: Universidade de São Paulo/ Faculdade de Medicina; 2005.
5. Health and human rights: a call to action on the 50th anniversary of the Universal Declaration of Human Rights. The Writing Group for the Consortium for Health and Human Rights. JAMA 280(5):462-464, 469-70.
6. Diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. Resolução n.º 196/96. Aprova as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos. [online]. Brasília: Ministério da Saúde/Conselho Nacional de Saúde; 1996 [acesso 16 Abr 2010]. Disponível: http://www.ufrgs.br/bioetica/res19696.htm.
7. Queiroz SRR, Bonacelli MBM, Mello DL, Jolo FS. O CNPq e o sistema de inovação em saúde no Brasil: uma análise a partir dos grupos de pesquisa do setor saúde. In: Memória do 22º Simpósio de Gestão da Inovação Tecnológica; 2002 Nov 6-8; Salvador [CD-ROM]. São Paulo: Núcleo de Política e Gestão Tecnológica da Universidade de São; 2002.
8. Ministério da Saúde. Biblioteca Virtual de Saúde [online]. [acesso Abr 2010]. Disponível: http://bvsms.saude.gov.br.
9. Instituto Brasileiro de Geografia e Estatística. Pesquisa Nacional de Saneamento Básico. Brasília: IBGE/Diretoria de Pesquisas/Departamento de População e Indicadores Sociais; 2000.
10. Hossne WS. O poder e as injustiças nas pesquisas em seres humanos. Interface Comun Saúde Educ 2003;7(12):55-70.

Received: 12.31.2009 Approved: 4.10.2010 Final approval: 4.16.2010

Contacts

Mary Lee dos Santos – *mary.santos@emescam.br*
Flávia Imbroisi Valle Errera – *flavia.errera@emescam.br*
Roger Bongestab – *rogerbongestab@yahoo.com,br* Elisardo
Corral Vasquez – *elisardo.vasquez@emescam.br*

Mary Lee dos Santos – Av. Des. Cassiano Castelo 70, Manguinhos CEP 29173-037. Serra/ES, Brasil.