Analysis of the involvement of bioethics in the professional activity of two institutions in Bauru, São Paulo

Patrícia Garcia de Moura1*
Silvia Helena de Carvalho Sales Peres2*
Renata de Almeida Pernambuco3*
Arsenio Sales Peres4*

1DDS
2DDS, MSc
3DDS, MSc
4DDS, MSc, PhD

*Department of Community Health, Bauru Dental School, University of São Paulo, Brazil; Hospital for Rehabilitation of Craniofacial Anomalies – HRAC, University of São Paulo, Brazil

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Abstract
This study quantified study projects involving human beings analyzed by the Research Ethics Committees (RECs) of University of São Paulo at Bauru, comprising the Hospital for Rehabilitation of Craniofacial Anomalies and Bauru Dental School. The projects were analyzed by retrospective observational study in a six-year period (1998-2003), in all study areas. The sample comprised 1,246 study projects, being 687 at HRAC and 559 at FOB. The numbers of projects analyzed each year at HRAC and FOB were, respectively: 1998 (54, 8), 1999 (72, 38), 2000 (130, 78), 2001 (66, 138), 2002 (191, 195), and 2003 (174, 102). Projects were divided into approved (587, 381), not approved (13, 10), pending (62, 109) and approved with recommendation (25, 59). Projects submitted to the REC of HRAC were mainly related to Speech Therapy (174), followed by Applied Social Work (58); with regard to the REC of FOB, 101 addressed the area of Speech Therapy, followed by Prosthodontics (n=71), Orthodontics (n=69) and Public Health Dentistry (n=65). The main reasons for returning of the projects were: informed consent term; methodology; consent from the institutions; explanation on financial resources; incorrect filling of forms; risk definition; timetable. It was concluded that the role played by RECs is fundamental, since they assure the requirement of autonomy, and the requirement to protect those whose autonomy is reduced.

Key Words: bioethics, research ethics, forensic dentistry.

Correspondence to:
Arsenio Sales Peres
Al. Dr. Octávio Pinheiro Brisola, 9 -75 V1
Universitária CEP: 17012-191
Telephone +55-14-3235-8357
E-mail: arsenio@usp.br
Introduction

During the 1970s, the term “bioethics” was introduced in a publication of Hossne & Vieira, through which new ideas were incorporated to the previously adopted term. Appearance of Bioethics as a “new” reflection has guided some definitions. Initially, it was included as part of Ethics, which is associated to the problems posed by the progress of medical sciences, yielding new problems or new considerations of old problems. Bioethics was also defined as an interdisciplinary study of the set of conditions demanded by any institution in charge of human life, considering the fast and complex progresses of knowledge and biomedical technologies. However, this definition should not be limited to an individual perspective, without any social and community relationship.

Ethics may be discussed from different perspectives. In its most superficial manner, ethics is only judgment, considering judgment as a verdict on a certain action. It should be mentioned that it follows a rule, which establishes the actions that may be performed, on the basis of principles.

There are four bioethical principles: autonomy, beneficence, non-maleficence and justice.

Autonomy should be considered from the standpoint of investigations in human beings by means of achievement of the informed consent term from the study subject. This represents one of the ethical bases for accomplishment of this type of study. The informed consent term assures the autonomy of the study subject.

Beneficence is related to a strict analysis between risks and benefits provided by the study, considering the maximization of benefits as ideal for development of investigations in human beings.

The non-maleficence is represented in studies in human beings when information achieved from previous studies in animals, in vitro or by computerized simulations is applied in human beings, which avoid the predictable damages.

The social relevance of studies in human beings and their distribution among study subjects and society indicates the principle of justice. The concept of equity, which is part of the main principle of justice, should be met by reduction of the charge to vulnerable individuals.

The matter of distributive justice was more widely discussed during the last 40 years, bringing about the discussion as to the assignment of resources for Public Health.

Bioethics should be pluralist, multi and transdisciplinary and not corporativist; it should be concerned not only with the scientific advances in the areas of health, life or environment, but also with the daily problems. Medicine has been practiced with authoritarism for decades. The Hippocratic oath, dated back to the fifth century BC, emphasizes the beneficence and secrecy, but does not mention the patient’s autonomy. In 1947, the Nuremberg Code was written by the Military Court in Nuremberg, on which the need to achieve the informed consent term from subjects included in clinical trials has been introduced. However, the primarily goal of the Code was the establishment of a set of rules to judge the atrocities made by the Nazis in the name of science. Other international documents have provided declarations and guidelines on investigation in human beings.

The National Health Council in Brazil has approved the regulating guidelines and norms of investigations in human beings by means of Regulation n. 196/96. The aim of the Regulation was not to restrict the freedom of work, but rather to assure the creation of controlling ethical mechanisms, providing conditions for effective operationalization with flexibility, for the effective practice of Bioethics, establishing a proper interface between the social control and administration, and not establishing aprioristic positions of prohibition nor total permission, providing legal force to the guidelines without the rigidity of legal dispositions, then establishing that all investigations in human beings should be submitted to evaluation by a Research Ethics Committee.

The Research Ethics Committees (RECs) should comprise a collegiate with at least 7 (seven) members. There must be participation of health professionals, exact, social and human sciences professionals, including jurists, theologians, sociologists, philosophers, bioethicists and at least one member from society, representing the users of the institution.

It should always have a multi and transdisciplinary nature, with no more than half of its members belonging to the same professional category and with participation of people of both genders. It may also have “ad hoc” advisors, people belonging or not to the institution, with a view to provide technical subsides. In the case of investigations on vulnerable groups, communities, and collectivities, an “ad hoc” member of the REC should be invited as a representative to participate in the analysis of the specific project. In investigations in indigenous populations, there should be a counselor familiarized with the culture and traditions of the community.
The assignments of the REC include revision of all study projects involving human beings, including multicenter studies, taking the primarily responsibility for the decisions on the ethics of the investigation to be conducted at the institution, so as to assure and keep the integrity and rights of individuals voluntarily participating in such studies; issue of written based reports in at most 30 (thirty) days, clearly identifying the trial, documents investigated and review date. The review of each project will lead to its classification into one of the following categories: approved, not approved, pending, approved with recommendation, and forwarded for analysis by the National Research Ethics Commission – CONEP/MS. It should confidentially keep all data achieved upon accomplishment of its assignments and file the complete process, follow the development of studies by means of annual reports from the investigators, play a consultative and educational role, stimulating the reflection on the Ethics in science, receiving complaints of abuses or notification on any adverse effects from the study subjects or any other party, which may interfere with the normal course of the study; require the establishment of inquest to the direction of the institution in case of complaints of ethical irregularities in the studies; and keep regular and permanent communication with the CONEP/MS. The National Research Ethics Commission acts as a normative instance of resources and coordination. The CONEP has 13 members from different areas, acting in a transdisciplinary manner, being that one of the members represents the users (study subjects). The CONEP is in charge of the final approval, after request from the REC, of projects on areas such as human genetics, human reproduction, investigations in indigenous populations, foreign collaboration investigations, research on biosecurity, research on new equipments and drugs, and researches comprising procedures not yet accepted as widely established in the literature. The study project should contain the following: cover, description, scientific background (studies, publications, investigations), risks/benefits, timetable, description of the responsibilities of the personnel involved, criteria for suspension of the study, structure required, budget and diffusion of results / destiny of the data and results, information on the study subject, qualification of the investigators and informed consent term. The informed consent term is the agreement achieved from the study subjects and/or his or her legal representative, after complete and detailed explanation on the nature of the investigation, its objectives, methods, predicted benefits, potential risks and discomfort, authorizing volunteer participation in the study. Brazil has 323 institutional ethics committees registered and further 121 are under way. No information was found in the literature reporting the amount of projects submitted or experiences of other Ethics Committees in similar institutions as those of the present study. Thus, the goal was to quantify the study projects involving human beings analyzed by Ethics Committees of HRAC-USP and FOB in the six-year period from 1998 to 2003, as well as to establish the contribution of RECs for preservation of the study subject.

Material and Methods
Data collection was conducted by means of reports designed by the Research Ethics Committees of the Bauru campus of University of São Paulo (FOB and HRAC), which addressed the projects analyzed in the monthly meetings and the respective report for development of the projects. The processes were analyzed by means of a retrospective observational study, for establishment of the profile of the investigations conducted at these institutions in a six-year period (1998-2003). The sample comprised 1,246 study projects evaluated by the Research Ethics Committees and made available by means of reports, in the period from 1998 to 2003. Data were analyzed by descriptive statistics, with utilization of absolute and relative frequencies, tables and graphs for presentation of the results.

Results
REC of the Hospital for Rehabilitation of Craniofacial Anomalies (HRAC-USP): 687 study projects were analyzed in 5 years: 54 in 1998, 72 in 1999, 130 in 2000, 66 in 2001, 191 in 2002, and 174 in 2003. From these, 587 (85.4%) projects were approved, 13 (1.9%) were not approved, 62 (9.0%) were pending and 25 (3.6%) were approved with recommendations.

REC of Bauru Dental School (FOB-USP): 559 study projects were analyzed in 5 years: 8 in 1998, 38 in 1999, 78 in 2000, 138 in 2001, 195 in 2002, and 102 in the first semester of 2003. From these, 381 study projects (68.2%) were approved, 10 (1.8%) were not approved, 109 (19.5%) were pending and 59 (10.6%) were approved with recommendations.

During five years of work, the Research Ethics Committees of the Bauru campus of University of São Paulo issued reports on 1,246 study projects, from which 255 (20.47%) required reformulation and alterations to adhere to the bioethical principles and to assure that the benefits to the study subjects were higher than the possible risks.

From the 559 study projects submitted to the REC of FOB, only 3 required forwarding to CONEP (the REC of the HRAC has no information on this issue).

The areas of study that submitted projects for evaluation were as follows:
- REC/HRAC: Biological Sciences (Clinical Analyses, Tropical Biology, Biochemistry, Physiology, Breathing Physiology, Physiology of Organs and Systems, Human and Medical Genetics, Immunogenetics); Health Sciences (Anesthesiology, Cardiology, Maxillofacial Surgery, Plastic Surgery, Reconstructive Surgery, Restorative Dentistry,
Discussion

Scientific investigation is so representative and important in society that the number of professionals dedicated to this job as significantly increased.20 The term research is related to a class of activities, the objective of which is to develop or contribute to the general or specific knowledge.21 Health professionals, when performing their activities, make use of information achieved by scientific investigations in their patients. The importance of investigations in health sciences is priceless, and utilization of human beings is required in some situations.

The Research Ethics Committees are in charge of considering and evaluating the uncertainties of the development of studies and weighing the conflicts in an impartial manner, taking care to protect the weakest party, which is often the subject or population under study. However, the investigator may also be vulnerable, when demanded by the research funding agencies, the competitive structure of investigations, and by prevalent values.22

The REC issues the report on the basis of information provided by the investigator in the study project. Several aspects are taken into account by the committees for evaluation, including weighing of the risks and benefits related to introduction of the project, or a specific chapter for this. The competence of the investigator for accomplishment of the study is also evaluated by the REC and demonstrated by the curriculum vitae of the investigator or investigators involved in the study. The letter of information to the patient and the informed consent term are also analyzed.

During the First Meeting of Research Ethics Committees of the State of São Paulo, the main reasons for returning of projects have been mentioned, including the informed consent term, which accounts for one third of the returns; doubts on the methodology employed; lack of consent from the institutions involved; poor explanation on the source of the resources required; incorrect filling of the forms required; definition of the risk to the study subject; timetable for accomplishment of the study with onset before approval by the Ethics Committee.

This study may guide future researches for investigation of the evolution of studies in human beings, as well as reduce the risks to the study subjects without impairing the evolution of researches. The Research Ethics Committee is related to investigations in human beings and assures preservation of the dignity of study subjects to the society, allowing constant discussion and adequacy of the concepts that form Bioethics. Thus, it constitutes a technical and scientific reflection on the plurality of society.

It was concluded that the growing increase in the number of study projects evaluated by the RECs from 1998 to 2003 demonstrated the importance of the REC in a Teaching Unit, guiding the studies and assuring the bioethical principles of investigations in human beings, assuring two moral requirements directly related to ethics in dealing with study subjects, namely the requirement of acknowledgment of autonomy, and the requirement to protect those whose autonomy is reduced. Return of the study projects may be avoided by careful preparation of the informed consent term, methods, consent from the institutions involved, source of the resources, correct filling of the forms required, definition of the risk to the patient and timetable for accomplishment of the study.

References