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Resolution 196/96 and the Brazilian ethical review system on research involving human beings

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Abstract

The objective of this paper is to analyze Resolution 196/96 from the historical aspects to its importance, repercussions and criticism. This study was elaborated through bibliographic survey of articles made available by the Virtual Health Library, by the Scientific Electronic Library (SciELO) and by Capes' Journals Website. It was possible to perceive, in the undertaken analysis, that there are still many challenges to be overcome by the CEP/Conep system related to Resolution 196/96 enforcement and CEPs operation. It was also noticed that this resolution and the CEPs develop a fundamental role in the social control by assuring respect and protection to researches subjects.

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

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Modern science emerged with the scientific revolution that was consolidated in 17th century, affecting investigation methods and objectives set by scientists. In this context, the science passes to be seen as knowledge produced by human reason in contact with nature through observation and experimentation. Scientific paradigm emerges due to the necessity of putting nature at service ‘ of the new human project of political-social transformation [1].

Despite this and the power then delegated to science, there were not until beginning of 20th century ethical norms that regulated researches involving live beings and, mainly, human beings. This aspect and the erroneous interpretation of some scientific theories – exemplified by Darwin's evolution of species theory and Mandel's hereditary characters theory – favored the development and support of eugenic theories. This scientific conjuncture and the historical context of the World War II

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provided, in this period, the undertaking of a series of experiments that committed the physical, mental, and psychological health of many people considered ethnically inferiors [2].

During the World War II experiments were carried out such as exposition of people to situations that simulted different atmospheric conditions, putting people in freezing tanks, generation and infections of wounds in different parts of the war prisoners' bodies to study cicatrization, and studies with twins to investigate genetic contribution in the development of normal and pathologic characteristics. These and other studies were undertaken without the consent of subjects of research and caused physical, mental, and psychological harms and until the death of thousands of people, culminating at the end of war, with the establishment of the Nuremberg Court, which judged some of the war criminals and elaborated the *Nuremberg Code* [3], the first international ethics standards for research involving human beings [2,4]. According with Sass [5], Vollmann and Winau [6] and Jonsen [7], the first ethical standard assumed by a modern State was the Regulations on New Therapy and Experimentation, published in 1931 by the German government (two years before Hitler became Chancellor). According with Jonsen [7], this document established the need of clear technical guidelines in Medicine, informed consent, analysis of risks and benefits, justification for the study of vulnerable populations, among other aspects related to ethics in research.

If these first standards on ethics in researches emerged only in mid-20th century, after the WW II, in Brazil research involving human beings started to normalized more than 20 years after publication of the first version of the *Helsinki Declaration*, from homologation, in July 1988,

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Resolution 1/88 of the National Health Council (CNS) – which had little practical impact. Seven years later, in 1995, it was noted the necessity to review the resolution. To that end, an Executive Working Group (EWG) was established, which made a previous consultation to scientific community at the Internet, and democratic accepted several suggestion to enrich the document, process that resulted in elaboration of Resolution 196/96 [8]. Despite been recent – instituted in 1996 – this resolution revealed increasing importance for the development of researches with human being in the country, particularly in creating a project evaluation system with national articulation, consolidated with the establishment of ethics on research committees (CEP).

In this scenario, one realizes that scientific researches, markedly those involving human beings, have multiplied and advanced vertiginously in Brazil, turning the role of ethics and of CEPs increasingly more important in all areas of knowledge, aiming at safeguard research subjects' rights and autonomy. In order to understand the importance dimension of Resolution 196/96 and of CEPs in scientific conjuncture, it is relevant to appeal to historical aspects that led to establishment of guidelines in research ethics involving human beings until Resolution CNS 196/96 – and also to analyze criticism to it and CEPs, as well as their importance in the Brazilian scenario.

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Thus, this article brings the following guiding questions: which historical aspects led to the establishment of guidelines in researches ethics involving human beings until Resolution CNS 196/96? What is the importance of Resolution 196/96 and of CEP in scientific conjuncture? Which are the criticisms to Resolution 196/96 and to CEPs? In order to answer these questions, the following objective was elaborated: to analyze Resolution 196/96 from the historical aspects to its importance, repercussions and criticisms.

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Methodology

This scientific article characterizes as a critical review of literature, therefore, of a qualitative character through bibliographic assessment carried out in electronic databases. To that end, we employed as means of data collection the search for text, books, and scientific articles, Master's degree thesis and PhD dissertations. We used as descriptors the terms of Resolution 196/96, ethics in research committee, the Nuremberg Code, the Helsinki Declaration, ethics and World War II, history and bioethics, ethics and science, importance and Resolution 196/96, importance and ethics in research. A The search for scientific articles took place during the period of August 2009 to January 2010 in periodicals in database of Bireme (Virtual Library in Health), SciELO (Scientific Electronic Library On Line), Capes Periodicals Web Sites, and in the pages of the National Ethics in Research Commission (Conep) and of the Ministry of Health (MOH) – in this agency were also used documents of F Series, Communication and Education in Health.

Fifty-eight works were identified, of which 17 were selected through previous reading of the abstract to comprise the bibliographic basis for this study, as most adequate to proposed objective. Due to complexity of the topic, time was not delimited, however, all articles found were published between 1999 and 2009. Bill no. 2.473/03, official documents on ethics in research of domestic and international origin, a book and a doctorate dissertation were used also – since they were considered as relevant for the approached topic.

During the search for articles, those that met, at least one of the criteria herein listed were selected: 1) to approach, in the Brazilian context, ethics standards in research involving human beings; 2) to carry aspects contributing for comprehension of the historical context of setting ethics in research guidelines involving human beings until Resolution 196/96 and the establishment of the ethics in research committees (CEP); 3) to relate ethics and science to the perspective of development of researches involving human beings; 4) to carry aspects that would contribute to understanding of criticisms to Resolution 196/96 and to the CEPs.

It is important to stress that, in order to complement our reflections, we used the professional experience of three of the authors of this article, members of a CEP, and of discussions carried out by two of them in research on CEP in the graduate program in Nursing and Health at the State University of Bahia (Uesb) [9-11].

Historical aspects of establishment of ethics in research guidelines involving human beings

The historical aspects that led to establishment of ethical guidelines involving human beings in Brazil pervade the world historical context until setting of Resolution 196/96 of the National Health Council.

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During World War II (1939-1945) much cruelty was done to war prisoners in concentration camps. These people were forced to participate in experimentations that cause suffering, extreme pain, physical disability, psychological problems and even death, showing that conflicts of interest between science and society could achieve unbearable levels that harmed human dignity [4,12].

Winner countries (United States, England, France and Russia) established, with the end of war, an International War Tribunal charged to judge crimes against humanity carried out during the period between 1939 and 1945. In addition to judging several war criminals, this court also prepared the *Nuremberg Code*, the first document having international guidelines on ethics in research.

The *Nuremberg Code* stresses the need of research subjects' voluntary consent and respect to autonomy. This document also establishes that participants need to be informed about the research in order to get needed knowledge for their decision, and it must be free of any form of coercion, among other basic aspects for the development of research involving human beings [3,12].

Despite war crimes left striking scar in the history of humanity, according to Costa [4] international guidelines on ethics in research, expressed in the *Nuremberg Code* were not widely employed by physicians and scientist in their researches, as they did not identified themselves with war criminals judged in Nuremberg for improper ethical behavior, which denotes that many researches carried in developed countries did not present acceptable ethical criteria.

This fact led the World Medical Association (WMA) to prepare in its 18th assembly, undertaken in Helsinki, Finland, the Helsinki Declaration, aimed at setting out ethical criteria to subsidize researches in medical area [4]. Despite to target clinical area, this document has common aspects with the *Nuremberg Code*, such the need of Professional qualification for the research development, of participants' clarification in relation to risks and benefits of research and in getting their free consent [13].

One underlines that throughout time, the Helsinki Declaration was updated and currently is in its sixth version, issued in 2008 [14]. Costa [4] and Kottow [15] call attention to the fact that, since 1999, several discussions have taken place targeted to modify the ethical guidelines of this document, and to establish double ethical standards, which consists in allowing the undertaking in peripheral countries (which do not have specific norms) of studies with use of placebo in human beings, considered as ethically inadmissible in developed countries.

Such discussions generated polemics and resulted in deep changes in 6th Helsinki Declaration text, written in 2008 [14], inclusively changes in document structure. Thus, the following changes were made in this new version: placebo use passes to be acceptable in situations in which the risk of harm is not considered as serious and researches subjects' access to benefits yielded by them started to be negotiable [15], which may place in risk the psychosocial integrity of many people that took part in international clinical researches and that already are in historical vulnerability due to the development stages of their countries of origin.

In this context, we must remember that, in face of changes undertaken in its text, the CEP/Conep System rejects the 6th *Declaration of Helsinki* VI [15], manifesting its position through Resolution 404/08 [16], which states that a new prophylactic, diagnostic, or therapeutic method must be tested comparing it with the best method in use, as well as that at the end of research, it must be assured to its participants the access to the best methods identified by the study.

The *Belmont Report*, although it is not an international document, elaborated between 1974 and 1978 by the National Commission for Protection of Human Subjects in Biomedical and Behavioral Researches in the United States has world relevance, as it contributed for bioethics academic consolidation, and it caused large impact by revealing the persistence of ethically arguable situations in research financed government agencies in that country [4]. It is important to remember that the document brought in three principles that became classics for bioethics or respect for people: autonomy or respect for people, beneficence, and justice [4,12].

The principle of autonomy means to respect the right, the capability of an individual to decide, without any form of coercion if he wishes or not to take part in research, which mandates that researcher has the obligation to inform him in clear and easily understanding language what the study is about [4,12]. In this sense, Kottow [15] alerts that one cannot mix up autonomy while universal anthropological attribute with the exercise of autonomy, which depends on many factors and is related to discerning capability and the vulnerability condition of research participants.

According to Rivera [12], the principles of beneficence and non-maleficence are complementary, as they imply in the compulsoriness that research must provide the maximum of benefits to its participants, to society and to scientific knowledge with minimum possible risks. The principle of justice requires that benefits and research risks be equally shared among research participants, treating individuals in accordance with their needs [4].

Repercussions of Resolution 196/96

Resolution 196/96 has scientific and social relevance since it established and normalized one of the most advanced research ethical review and control system involving human beings in Latin America : the CEP/Conep system.

This system comprises regional instances, ethics in research committees (CEP), and one federative instance, the National Ethics Commission (Conep), national research involving human beings control agency [16]. Additionally, this resolution guides the ethical aspects that must be observed in research protocol and sets that every research involving human beings , independently of the knowledge area, be appreciated by a CEP [17].

According to Resolution 196/96 [18], Conep is a collegiate agency with advisory, deliberative, and independent agency, linked to the National Health Council and endowed with a multi and transdisciplinary composition with both genders individuals. In 2009, Resolution 421 [19] altered its composition regarding the amount of its members, aiming at assuring representation of one councilor from management segment, one from workers, and two from users segments, also changing the number of its members from thirteen to fifteen.

In addition, according to Resolution 196/96, Conep has attributions such as the stimulus for establishment and registration of CEP, approval and follow up of research projects in special thematic areas (which do not have specific legislation and/or need Conep appreciation to be developed), the supply and dissemination of specific norms in ethics realm, the constitution of an information and follow up system on ethical aspects of research with human beings, among other attributions [18].

It must be stressed also that, in 2001, Conep created the National Research Ethics Involving Human Beings System (Sisnep) with the objective of establishing a national information and follow up system of the ethical aspects of researches undertaken across the Brazilian territory. This system is very useful as it facilitates social control of researches and data analysis of interest of the Ministry of Health and of agencies related to Sciences and Technologies policies [20]. Nevertheless, despite its eight years of existence, Sinep does not cover the totality of CEPs existing in Brazil.

This fact and the existence of Sinep limitations for following up researches with human beings show the need of Sinep review. Thus, in 2007, the National Health Council deliberated on the construction of a new and more complete researches follow up system, denominated as Platform Brazil [21].

Platform Brazil is a national and unified basis of registry for registry of researches involving human beings, which aims at integrating all CEPs and Conep, and also allowing integration with regulatory agencies and foment to research, international institutions, scientific editors, among others, in addition to provide information on the several stages of researches: project stage, field stage, and the reports on already completed researches, since one of its main objectives is to act as a social control tool capable to provide the analysis of the historical situation of researches and the follow up of its execution [21].

This platform will be comprised by modules. The first two, Public and Researcher, integrating the first stage of its development, were launched by Conep in December 15, 2009, in the Emilio Ribas Auditorium, of the Ministry of Health [21], but they are not operational yet.

The Ethics in research committee is an interdisciplinary, interdependent collegiate with public function that is part of social control mechanisms organized on science practices and to seek for humanized treatment of research participants, since its mission is to safeguard their rights and dignity in order to their interests be considered above the interests of science and of society, markedly of more powerful social groups [22].

From the scientific standpoint, CEP has the advisory and educational role by contributing for researches quality and to promote discussions on their ethical aspects, and its role in the institutional development, collaborating toward valuation and recognition of ethically suitable works [23]. CEP attributions are to review all research protocols involving human beings, inclusively the multicentric, to issue consubstantiated opinions on approved research projects, to perform an advisory and educational role, to receive denounces on research involving human beings, to maintain communication with Conep, among other attributions [18].

According to Kipper and Oliveira [24], Brazil's first CEP was the Ethics in Research Committee of the Pontifical Catholic University of Rio Grande do Sul (CEP-PUCRS), created in May 17, 1990, still under Resolution CNS 1/88. The authors [24], in their study on CEP-PUCRS experience report as major positive points the educational role of ethics review of projects, the partner's role and not persecutor, the increase in quality of research projects, the advisory provided to other institutions, and participation in Conep, and the recognition and credibility acquired by CEP among researchers and research fomenting agencies.

Limits and criticism to Resolution 196/96 and to CEP

According to Diniz and Guerriero [25], since the 1980s several discussions are developed internationally between biomedical and social areas of knowledge on the transposition of rules adopted by CEP in biomedical Project analysis for projects in human and social sciences, markedly those qualitative ones. In Brazil, due to increasing obligatoriness of submitting projects to CEP to get financing and/or to publish researches outcomes, such discussions have become more intense and deepened, inclusively arising biomedical dilemmas concerning the conducting of many researches and the dissemination of their outcomes. Thus, due to complexity and amplitude of these discussions, we will mention just some points, since it is impossible to exhaust them in only one topic of an article, although we believe that mentioning some of these points has fundamental importance to reach the objectives of this article.

Much of the criticism to Resolution 196/96 and also to the way of acting of the CEP in projects analysis come from human and social sciences researchers, for whom this resolution is biocentric, targeted to the mould of biomedical research, not considering the difference existing in research in human beings and with human beings [26]. According to Guerriero [26], in research in human beings it is possible to previously define methodological procedures to which research subjects are socio-cultural entities, which often makes difficult or even impossible to previously outline some methodological procedures, since many of them are built along with the research.

Cardoso de Oliveira [27] clarifies still that research with human beings, undertaken in social sciences, involve an interlocution relationship between researcher and research subjects, while research in human beings in biomedical areas, an intervention relationship, which requires that research subject to have the maximum knowledge of what research consists and its implication and/or consequences to his wellbeing.

Porto [28] considers that every research, independently of the knowledge area, involves human beings, even if it is only the researcher himself, what, for this author, makes the term *involving* pleonastic. Despite this, he reports that the expression *research involving human beings* has been used in the intention to deal with ambiguities such as genetics research, which not always can be considered research in human being or research with human beings. In this context, although he does not propose extinction of these concepts, Porto alerts for the fact that maintenance of classification of types of research in *with* or *in* human beings, in detriment to the idea of involving human beings, proposed by Resolution 196/96, may provide the development of unscrupulous strategies by big corporations that finance research aiming at getting high profits.

It is important to remember that although in research in human beings (laboratorial) all procedures have to be previously outlined to assure reproductivity, reliability of outcomes, and the safety of subjects, and also of the researcher, during its development events may take place resulting in the necessity of changing methodological procedures to ensure subjects safety and experimentation feasibility.

Another aspect to consider is the fact that human being is biopsychosocial being, which means that he is not restricted to biological dimension, but is complex, also having psychological, social, and moral dimensions. This allows realizing that even research working only with observation, interviews, and questionnaires may bring risks and/or discomfort in as much as a question and/or interpretation of the observation may interfere negatively in research subject's life, and cause him some loss. This aspect also shows that these researches must be submitted to a CEP; nevertheless, as they have peculiarities diverse from clinical and laboratorial researches, they require from CEP a look that considers such peculiarities at time of appreciating the Project and discussing the opinion.

Para tanto,It is indispensable, to this end, that CEP members are continuously getting capacity building among themselves, since, according to Diniz and Guerriero [25], osthe ethical principles present in the scenario of researches are universal, allowing identification of involved ethical aspects in human and social sciences research, and their handling in such way that all involved are respected: ,researched, researcher, and community [26].

In this context, Guerriero [26] remembers that, although research in human and social sciences incorporate ethical aspects in its scientific making, it is difficult to apply Resolution 196/96 to many of them, which may lead to disregard by this resolution of many ethical aspects relevant in other areas of knowledge, which are distinct of the biomedical area. Such application difficulties reside mainly in the fact that this resolution is targeted for quantitative research of experimentation character.

The obligatoriness and the moment of signing the free and clarified consent term (FCCT) are questioned also by many authors [25-29], who remind that, in many types of research, markedly in the área of Anthropology, it is necessary establishing a link of trust between researcher and researched, been this an important part of the data collection process. In these types of research., the request of signing FCCT before initiating data collection would make difficult to establish a Bond and, consequently, collection. Guerriero [26] and Diniz and Guerriero [25] advocate that, in such situations, the signature of FCCT be requested at the end of collection, while Cardoso de Oliveira [27] remembers that, in Anthropology research, the research subjects' consent is expressed in the informed engagement in speaking with the researcher on investigated topic, while, therefore, a tacit or implicit consent, without the need of getting it registered in a document or formal act.

Macrae and Vidal [29] question also the obligatoriness of FCCT in research with hidden populations that undertake practice considered illicit, such traffickers, drug users and criminals, since, according to authors, is very difficult that people in this context accept to sign or provide their digital Mark in FCCT and that, when signature is gotten, one cannot ensure its veracity. There is also the possibility that Police investigations intimidate researcher to collaborate, compromising assurance of secrecy present in Resolution 196/96, or to be sued for denying collaborating due to the commitment assumed with participants in his study [25].

Additionally, one should be mentioned that, despite Resolution 196/96 specifies that the outcomes of studies should be disseminated even if they are unfavorable [18], many agencies of fomenting research and periodicals make it difficult or do not permit that unfavorable outcomes to be published. Diniz and Guerriero [25] remember also that it is in the dissemination of results stage that many ethical challenges of research are found, such as assurance of secrecy and anonymity (mainly when it refers to research subjects with single representation such as a health secretary or the chairman of a corporation, for example), devolution of outcomes, sharing of benefits and ideas of fair representation, among others.

Another aspect worth noticing is Bill No. 2,473/03, authorship of Representative Colbert Martins [30], which aims at changing Resolution 196/96 into law. The referred Project has justification of its approval as the Double ethical Standards, the participation increase of Brazilians in research with new drugs, the non-compliance with ethical norms, difficulties in following up approved projects by research ethical control, the fact of Conep and the CEPs been the sole responsible for the ethical control of research, and still, of Conep only appreciating projects of special thematic areas and/or that they do not have specific resolution. Also, it is important to mention that Bill No. 78/06

(under appreciation), authorship of Senator Cristovam Buarque [31], which aims at establishing penalties for breach of guidelines and norms concerning research involving human being, and it mandates co-responsibility of researcher, promoter, and the institution for indemnification due to research subject for eventual harm or loss.

It is argued that changing Resolution 196/96 into Law could turn bureaucratic the CEP/Conep System, since Brazilian judiciary system has already a large demand of cases, which, often take years in legal processing. Additionally, one cannot evidence that penal sanctions would be more effective than educational measures in enforcing ethical norms, since many researchers do not have in their academic trajectory any approach on research ethics. It should be stressed also that, concerning Bill No. 78/06, by establishing penalties it does not consider the existence of different types of research and, therefore, different levels of discomfort and/or risks for research subjects, and it does not specify how evaluation of the causal nexus would occur, as well as the extent of ham caused by research.

One cannot forget that the CEP/ Conep System is considered as one of Latin America most advanced, only needing to be enhanced through the establishment of strategies targeted to follow up approved projects, CEP infrastructure and their inspection by Conep, as well as to consolidate the educational role of CEPs, and to invest in continued capacity building of their members. Thus, before thinking in punitive strategies, it seem more coherent to us to think in strengthening strategies of the CEP/ Conep System aimed at making social control in research more broad and effective.

Concerning ethics in research committees, much criticism relies in the difficulty of enforcing

Resolution 196/96 expressed in the delay at issuing opinion (which often surpasses the period of thirty days set by the resolution), in the difficulty of following up the development of approved projects [13], in precarious infrastructure of many CEPs and in the reduced number of staff. This criticism coadunate with Kipper and Oliveira [24] by reporting some of the difficulties experienced by Brazil's first CEP: the lack of uniformity in the requirement level of CEP, alack of uniformity of evaluation by Conep's reporters, the large number of projects submitted for ethical review and the existing hindrances to follow up approved projects.

The difficulties of CEP can be explained by demand above its evaluation capacity, by lack of experience of their members, lack of institutional support, and in the lack of interest of institutions in constituting new CEP, since the institution in which it is implemented should supply all infrastructure, consumables and staff for developing its activities [9,10,32].

One should highlight also that the work of CEP members is voluntary, what, although it is an important feature from the standpoint of social control in research, has risen discussions on the possibility of their remuneration, as the ethical review of projects, due to increasing demand, has generated increased work for the opinion makers – Who have to reconcile projects review and presence in meetings with their professional work, causing in some CEPs difficulties in meetings quorum and delays in issuing opinions [9,32]. An alternative would be reducing work hours of opinion makers linked to higher education and research institutions. Nevertheless, it would remain the challenge of sensitizing CEP members' employers, representatives of the community (just as SUS users' representatives) about the importance of donating part of work hours of their staff to CEP.

It is relevant to mention that the large demand of projects in many CIP, mainly in those present in the interior of regions such as the Northeast and North regions of Brazil, come mostly from the non-existence of CEP in the majority of higher education and research institutions [9,10]. We consider the large demand as the one of most serious problems of CEP, as this agency should be a reflection, discussions, education, and enhancement space for its members for the consequent improvement on the quality of their ethical analysis.

However, the large demand of projects often relegates these activities to a second level, jeopardizing the dynamics of CEP work [9-11,32]. Despite this, we think that, and nonetheless the difficulties faced and considering also the possibilities, the CEPs should assist researchers of the institutions that do not have CEP, for respect to them and, mainly, to the research subjects of these projects. This also means that it is necessary to sensitize institution on the importance of constituting CEPs.

The implementation of a CEP demands costs and it does not have direct finance return to institution which makes that the relevance of its constitution and work is not noted by many researchers and institutions. Nevertheless, CEPs are crucial for enhancement and consolidation of research involving human beings, independently of the area of knowledge, evidencing the legitimate vocation for the research of institutions in which they are installed [23].

Discussions about the diversity and particularities of research and criticism to Resolution 196/96 and to CEP work raise a series of challenges. Some of which are: change in projects analysis practices by the CEPs; establishing discussions with the most diverse areas of knowledge with intention of knowing how they would like to be understood in the ethical review of their projects, greater participation of researchers in human and social sciences areas, elaboration of specific guidelines for human and social sciences areas [25,33-35].

It should be highlighted that it also constitute challenges to be overcome the lack of knowledge of CEPs by researchers and the their little sensitization concerning the necessity of ethical review of projects, which often derives from the absence of approaches in ethics on research in their academic trajectory and of the small number of scientific events about bioethics and ethics on research [9].

The importance of Resolution 196/96 and CEPs in undertaking research involving human beings

It is indispensable to stress, despite criticism and limitations, the importance of Resolution 196/96 and of the work developed by CEPs related to their role in social control of research and in assurance of protection and respect for research subjects, which has been enabled by the voluntary work of CEP opinion makers members.

It should also be stressed that all research, independently of the area of knowledge, to be submitted to CEP, despite still existing limitations in Resolution 196/96 and in CEPs appreciation rules to analyze projects from different areas of knowledge, since the human individual, per excellence, is biopsychosocial and endowed with a complexity that cannot be understood without the interweaving of the most diverse areas of knowledge.

Additionally, ethical review of research projects contributes not only for data collection process, but also for perfecting of these in all of their stages, inclusively for the stages of analysis and interpretation of results, as correspondence between objectives, methodology, and collection instruments also are part of the ethical aspects of research.

Some researches cannot be outlined, at start, by the researcher, since, to this end, the later needs to go to the field and know the existing reality for data collection, as it happens with many research in human and social sciences.

In these cases, if the research complies to ethical aspects, at the end of the study, respect and protection conferred by researchers to research subjects in all of its stages will be evidenced, as well as the correspondence between objectives, methodology, and data collection instruments. In such situations, it seems to us that ethical review of projects by CEP should be undertaken, respecting research particularities, with constant follow up of project development.

We understand, based in reflection carried out from mentioned bibliography, that Conep, throughout the years, has committed in minimizing limitations and improving the CEP/Conep System, and that the establishment of discussions and the engagement of researchers from the most diverse areas of knowledge point to the setting of actions that target minimizing these limitations. In this sense, Jorge er all [36] remind that Conep has stimulated the undertaking of CEP dissemination events (such as the National Meeting of Ethics in Research Committees-Encep) and the discussion in ethics on research with researchers from institutions that undertake researches.

Additionally, the fact of CEP are agencies of multi professional character also can contribute toward these actions, since the most diverse areas of knowledge, even if in lesser proportion, are part already of the CEP/Conep System, which signals that since the constitution of this system, there was already concern in contemplating all areas of knowledge.

Garbin et all [37] highlight that CEP/Conep configures as a system under construction and perfecting with intention of follow up scientific-technological changes and the changes of the Brazilian society thought, markedly the scientific community. These authors remind, still, that the CEP/Conep System and the growing necessity of ethical review of projects has placed Brazil ahead of other Latin American countries and of many other less developed countries in the planet.

Finally, we must remember that Resolution 196/96 and the CEP contribute for the consummation of the deliberative democracy and the ethical review of research projects supposes a careful and systematic reflection, that relies in two crucial aspects: the relevance of research and its consequences for all involved (researched and researcher) placing the research subjects in the condition of citizens and science under the riddle of society, which shall be benefited by research, which means that the ethical aspects of research must be faced seriously during its entire development: from project ethical review and follow until submission of the report to CEP [38].

Thus, one realizes that the importance of Resolution 196/96 and CEPs does not relies in the application of norms and rules, but in a set of actions that target assuring the respect and protection of research subjects while human individual, biopsychosocial being, endowed with biological body but also (and not less important) of rights, necessities, fragilities, insecurities, certainties, yearns, anguish, beliefs, expectations, dreams, independently of ethnic group, culture, nationality, sex, social status and schooling.

Final considerations

Science needs always to make a counterpoint with ethics in order to not losing sight of its function of generating benefits and to be reduced to scientific making by mere curiosity or status, which means that Resolution 196/96 and CEP constitute indispensable instruments for undertaking research involving human beings, independently of the area of knowledge, and they place Brazil ahead of many countries concerning ethical standards in research, which can be evidenced by the fact that the CEP/Conep System is considered as advanced by many researchers.

Despite this, criticism to Resolution 196/96 and CEP, mainly because this resolution is targeted for experimental research of quantitative character and the way ethical review of research projects in human and social sciences areas, which do not feel themselves contemplated by the CEP/Conep System. Such criticism derive from the great diversity of areas of knowledge and types of existing research and of the fact of bioethical problems involving biomedical research have been the motors for creating this resolution and of other documents in ethics on research.

We think that, concerning operational difficulties of CEP, they demand more time to be solved, since they need sensitization of institutions and researchers, mainly about implanting new CEPs. Nevertheless, we remind that solving these difficulties is of vital importance for the development of research and for consolidation of Brazil as an acting country in the international scientific realm.

We highlight the role of Resolution 196/96 and CEPs while instruments of social control in research and the multi professional character of CEPs, which contributes for the enrichment of ethical reflections about projects, shows their democratic vocation and points toward the development of a more pluralist view regarding research.

Finally, we remind still that there are many challenges to be overcome by the CEP/Conep System concerning application of Resolution 196/96 and of CEP work, many of which were quoted in this article, but we stress that the crucial importance of this resolution and of the CEPs consists in respect and protection of research subjects seen not as means to achieve the objectives of research, but as participants of the research, which they are above all, and mostly human individuals that must be considered in their biopsychosocial complexity, and respected in their rights, necessities, fragilities, insecurities, certainties, yearns, anguish, beliefs, expectations, and dreams, among other aspects.

Resumo

A Resolução 196/96 e o sistema brasileiro de revisão ética de pesquisas envolvendo seres humanos

O objetivo deste artigo é analisar a Resolução 196/96 desde os aspectos históricos à sua importância, repercussões e críticas. Este estudo foi elaborado mediante levantamento bibliográfico de artigos disponibilizados pela Biblioteca Virtual em Saúde, pelo *Scientific Electronic Library* (SciELO) e pelo Portal de Periódicos Capes. Na análise realizada foi possível perceber que ainda há muitos desafios a serem vencidos pelo Sistema CEP/Conep no que concerne à aplicação da Resolução 196/96 e ao funcionamento dos CEP. Notou-se também que esta resolução e os CEP desenvolvem papel fundamental no controle social ao garantir o respeito e proteção aos sujeitos das pesquisas.

Palavras-chave: Ética em pesquisa. Comissão de ética. Revisão ética. Bioética. Ética.

Resumen

La Resolución 196/96 y el sistema brasileño de control ético de la investigación con seres humanos

El objetivo de este artículo es analizar la Resolución 196/96 desde los aspectos históricos hasta su importancia, repercusiones y críticas. Este estudio fue elaborado mediante pesquisa bibliográfica de artículos puestos a disposición por la Biblioteca Virtual en Salud, por la *Scientific Electronic Library* (SciELO) y por el Portal de Periódicos Capes. En el análisis realizado fue posible percibir que todavía hay muchos desafíos a ser vencidos por el Sistema CEP/Conep en lo que concierne a la aplicación de la Resolución 196/96 y al funcionamiento de los CEP. Fue notado también que esta resolución y los CEP desarrollan un papel fundamental en el control social al garantizar respeto y protección a los sujetos de las investigaciones.

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

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Authors' participation in the article

Adriana Barbosa wrote the text, Rita Boery, Eduardo Boery and Edite Sena were responsible for correcting the text, Douglas Filho was responsible for correction of text and review of Portuguese language, and Alaide Oliveira helped in writing some paragraphs.