Reflexion Article

Difficulties and challenges in reviewing ethical aspects of research in Brazil

Dificuldades e desafios em revisar aspectos éticos das pesquisas no Brasil

Dificultades y desafíos en revisión de aspectos éticos en investigación en Brasil

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ABSTRACT

Objective: To reflect on the problems faced by researchers from different areas, especially of Humanities and Social Sciences, when submitting research projects for evaluation by the research ethics committees in Brazil.

Method: A theoretical and reflective study based on international literature and the critical analysis of the authors.

Results: Although Resolution 466/2012, which addresses human research, contains some innovations, issues related to the research participants remain obscure and the project evaluation process is time-consuming.

Conclusion: The difficulties faced by researchers, especially in the fields of Humanities and Social Sciences, must be transposed to ensure that the ethical guidelines are applicable, in terms of principles and procedures, to the different research traditions. Appropriate human research standards must be managed by a system with a satisfactory operational capacity, according to the specificities of the different areas of knowledge.

Keywords: Human experimentation. Ethics, research. Research.

RESUMO

Objetivo: Refletir sobre os problemas enfrentados pelos pesquisadores de diferentes áreas, sobretudo de Ciências Humanas e Sociais, durante o processo de avaliação dos projetos de pesquisa pelos Comitês de Ética em Pesquisa no Brasil.

Método: Estudo teórico-reflexivo, baseado na literatura científica e análise crítica dos autores.

Resultados: Embora a Resolução 466/2012, que trata de pesquisas com seres humanos, apresente inovações de conteúdo, ainda permanecem obscuras questões relacionadas aos participantes de pesquisa, além do moroso processo de avaliação dos projetos.

Conclusão: Dificuldades enfrentadas por pesquisadores, principalmente de áreas como Ciências Humanas e Sociais, precisam ser transpostas para que as diretrizes éticas se tornem aplicáveis, tanto em termos de princípios quanto de procedimentos, às distintas tradições de pesquisas. É premente que as normas regulamentadoras de investigações com seres humanos sejam gerenciadas por sistema com capacidade operacional satisfatória, considerando as especificidades das diferentes áreas do conhecimento.

Palavras-chave: Experimentação humana. Ética em pesquisa. Pesquisa.

RESUMEN

Objetivo: Reflexionar sobre los problemas que enfrentan los investigadores de diferentes áreas, especialmente de Humanidades y Ciencias Sociales durante el proceso de evaluación de los proyectos de investigación por parte de los Comités Éticos de Investigación en Brasil.

Método: Estudio teórico y reflexivo basado en la literatura y análisis crítico de los autores. Resultados: Aunque la Resolución 466/2012, presente innovaciones de contenido, siguen oscuras algunas cuestiones relacionadas con los participantes de investigación, además del largo proceso de evaluación de proyectos.

Conclusión: Las dificultades que enfrentan los investigadores, especialmente de áreas como Humanidades y Ciencias Sociales, necesitan ser incorporadas donde las normas éticas sean aplicables, en términos de principios y de procedimientos, a las tradiciones distintas de investigación. Es urgente que los estándares apropiados de investigación con seres humanos sean administrados por sistema con capacidad operativa satisfactoria, teniendo en cuenta las especificidades de las diferentes áreas del conocimiento.

Palabras clave: Experimentación humana. Ética en investigación. Investigación.

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INTRODUCTION

In Brazil, the first resolution on human research was created by the National Health Council (CNS) in 1988 to define the ethical requirements for studies in the area of health. At the time and also for the first time, the need for Research Ethics Committees (CEPs) and the submission of research protocols reviewed by such committees prior to the start of the study was identified[1]. A few years later, in 1996, Resolution 1 of 1988 was revoked and number 196[2] was established. The new resolution was considered a landmark in the regulation and control of ethical research in Brazil because it stipulated that all studies with humans must be submitted and reviewed by a CEP under the responsibility of the National Research Ethics Commission (CONEP)[1].

With the aim of reinforcing social control in favour of research subjects, modernising the definitions and terms, and updating bioethical benchmarks, a public consultation was launched for Resolution 196/1996 for 60 days, in 2011. In September 2012, a workgroup organised by the CNS examined the proposals and created a document with representatives of most Brazilian CEPs that was approved by the organ and published as Resolution 466/2012 in 2013[3].

The ethical aspects of human research are a constant concern although difficulties persist. This context led to the creation of the following guiding question: What are the problems faced by Brazilian researchers during the research project evaluation process of the CEPs and what are the challenges to be overcome in this field? The aim of this paper is to address the problems faced by researchers from different areas, mainly Humanities and Social Sciences (HSS), during the research project evaluation process of the CEPs in Brazil.

METHOD

A theoretical-reflective study based on the discursive formulation of the subject grounded in national and international scientific literature and the critical analysis of authors. The theoretical construction of reflexive thinking[4] was adopted to address the conceptual and historical aspects of resolutions 1996/196 and 466/2012 and discuss problems currently faced by researchers, particularly in the area of the HSS.

RESOLUTION 196/1996 VERSUS RESOLUTION 466/2012: HISTORICAL AND CONCEPTUAL ASPECTS

Resolution 196/1996 was paramount for the guidance and regulation of human research because it created and standardised one of the most advanced systems of Latin America to review and ethically control these studies: the CEP-CONEP[1]. The creation of ethical resolutions and the installation of the CEPs are not merely considered landmarks because they allow the application of standards and rules, but, above all, because they ensure respect and protection of research subjects as biopsychosocial beings and contribute to the establishment of deliberative democracy. They require careful and systematic reflection supported by two fundamental pillars: the relevance of the research and its consequences for everyone involved, thus placing participants in the condition of citizens and science under the scrutiny of society, which should be benefited by research[5-6].

Despite the benefits of compliance with ethical guidelines, elaborating these guidelines is a challenge in terms of principles and procedures due to the wide range of areas of knowledge[7]. Resolution 466/2012 allowed some innovations, such as the expansion of ethical aspects of human research, especially the compulsory signature of the participants of the informed consent statement, which is now considered "process of free and informed consent" or the approval of participants (approval statement) in the case of those who do not have legal autonomy (child, teenager or legally incapable individual). Also, the new resolution updated the terminology and definitions (25 in all), including "research subject", which came to be called "research participant", and "research sponsor", which is the term used to define individuals who fund the study[3, 7 -8]. With regard to the ethical analysis procedure, the option "approved with recommendation" was removed. Thus, CEPs and the CONEP must issue opinions and classify them as "approved", "pending" or "failed".

The CEP-CONEP System

The fact that the CEP-CONEP system needs reforms and the interest of authorities to effectively implement the system has been acknowledged since 2008[9]. At that time, the most significant initiatives included the implementation of a national, unified system of human research records called "Plataforma Brasil" or Brazil Platform. The system was adopted to streamline ethical reviewing of CEP protocols and it allowed the computerisation of procedures of the CEP-CONEP, the integration of information between the researcher, the local committee and the national Committee, and follow-up in the different stages of research[3].

However, some problems persist. In comparison to other countries, Brazil faces the duplicity of ethical evaluation, namely, the need for projects of the so-called thematic

areas to undergo the scrutiny of CONEP after approval of the local CEP. This process is still in force for projects of specific areas and projects with foreign cooperation, regardless of the area[9]. This is an unprecedented requirement since no other country that produces clinical research adopts a similar system. Although it is recognised that the double evaluation system (CEP-CONEP), and often multiple evaluation systems as in the case of multi-centre international projects (overseas CEP, coordinator CEP, CONEP, local CEP and, depending on the nature of the project, ANVISA) can provide additional protection for the research participants, avoidable inefficiencies have been detected partly due to inconsistencies between the opinions of these multiple committees. Furthermore, one of the main factors that delay the approval of international clinical research projects stems from this multiple ethical evaluation[9].

Therefore, there is an urgent need to decentralise the CEP-CONEP system, that is, to fully delegate project approval to the CEPs and restrict the competence of CONEP to supervision, monitoring and appeals to reduce the inefficiencies that hinder Brazil's full capacity to produce knowledge[9].

Until the model used in Brazil is changed, delays in obtaining regulatory approval for clinical research can be three times longer than in North American or European countries. This delay is troubling because it restricts scientific return and creates obstacles for research funding, with repercussions on the economy and quality of life of the population. Another important step is the implementation of the institute's tacit approval: if the regulator does not manifest an opinion within 60 days, the project must be considered approved (tacit approval), which occurs by legal ordinance in all countries of the European Union[9].

The poor quality of the research submitted to the CEP-CONEP system is also noteworthy. Flaws in the preparation of protocols, lack of compensation to volunteers, non-compliance with bioethical standards and informed consent statements and poorly written and unclear approval statements, all of which are the responsibility of the researchers, slow down the evaluation process. Other issues such as the non-professionalisation of the CEPs and absence of quality evaluations of the existing CEPs also contribute to the delays and long lead times of the ethical review process[5].

Problems encountered by researchers during the approval of projects by the CEPs

Since Resolution 466/2012 follows the same logic as 196/1996, HSS researchers are still struggling with the CEP-CONEP system due to the inadequacies in the conception of research in life sciences that is incorrectly applied to other domains, and the procedures established by Brazilian guidelines for the ethical review of qualitative health studies. The consequences of these inadequacies are numerous and have been widely discussed without any clear solutions[10]. For the analysis and approval of qualitative proposals, for example, delays are caused by the submission of unfounded questions to the researcher, such as "notify your sample calculation" and "the number of respondents is irrelevant". Such requirements reveal a lack of knowledge of the theoretical and methodological specificity of empirical social research and do not contribute to the ethical reviewing of the research[7].

Although the advent of Plataforma Brasil sought to increase the solvability of the CEP-CONEP system, this tool has been criticised because its format still focuses on biomedical research, which creates difficulties for HSS scholars. The specificity of the platform is reproduced in the CEPs, where sensitivity and knowledge are essential to suggest and accept adjustments in relation to the completion of the form items, in order to contemplate the assessment of the non-biomedical projects of the larger areas of knowledge of Group III of the CONEP[11].

Another aspect that is criticised is the strict application of the compulsory consent statement when it is impractical, as in the case of research involving criminals or studies on practices that are illegal in Brazil, such as abortion[11]. The HSS have specific ethical dimensions that almost exclusively depend on the insertion of the researcher in the community and the relationships he or she establishes with research participants[12-13]. The Brazilian Anthropology Association (ABA) has participated in discussions about the transposition of the rules adopted by the CEPs to analyse biomedical projects to those of the HSS, notably of a qualitative nature[12].

It should be noted that the nature of research with humans is heterogeneous and the relationship of the researcher with the study participants is not the same in different scientific communities. Moreover, the HSS have specific research conceptions and practices that carry a pluralist sense of science, and address the attribution of meaning, practices and representations without direct intervention with the research subject and with a specific nature and level of risk. The researcher-participant relationship in this kind of research is continuously established during the investigation and can be redefined at any time in the dialogue between subjectivities, which implies the construction of hierarchical relationships. This specificity has frequently created difficulties in ethical reviews[7].

In addition to the above-mentioned issues, researchers of the HSS claim that the change in Resolution 466/2012 was merely timely and only replaced one research definition with another definition without any consideration for its implications and consequences[7, 10-11]. Bioethical reviewers have difficulties in examining research of the HSS and argue that the terms of Resolution 466/2012 cannot always be immediately applied to the analysis of those projects under ethical consideration. This situation has caused delays or the non-approval of these projects, even when there are no ethical improprieties[7, 14]. Contrarily, Resolution 466/2012 maintained the organisational structure of the CEP-CONEP system and enabled specific advancements, including a possible complementary resolution to meet the specifics of research in the HSS[7, 14], which was one of the major contributions of Resolution 466/2012 to these fields. As predicted, a workgroup was formed in 2013 to create this complementary resolution with the representatives of CONEP and other associations and research societies in several areas of knowledge, such as the ABA[11].

New achievements in these areas, within the scope of the CEP-CONEP system, would also be possible according to the additional draft of the resolution published in October 2014. Among other items, the document establishes the non-obligatory application of the written consent statement and full dismissal in specific cases; the various levels of risk in research and their respective specifications; the distinction between material and immaterial damage; and the possibility of unburdening the CEP-CONEP system and of strengthening the ethical and methodological review of research in these areas[15]. However, some points of the draft lack clarity, such as the specification about what the resolution defines as different levels of caution. It is also important to better define and list which criteria will be adopted by the CEPs to check the level of risk by the CEP secretariat; to explain that the researcher, whose project with minimal risk has been chosen for review by the CEP, must be immediately reported using Plataforma Brasil; and to specify how research with be treated in the interface between the HSS and other areas of knowledge[10-11].

The key point of discussion on the ethical standardisation of research lies in the use of the term/concept of "risk" and the classification of risk levels, which are the object of disagreements between the HSS and the Biomedical Sciences[10]. Another criticism of the draft during the CEP national meeting held in November 2014 was that it does not observe transdisciplinarity. On the occasion, the attendees discussed whether the existence of a resolution for the HSS and the CEPs for these areas could lead to the division of disciplines[10]. Despite the need to improve the CEP-CONEP system, it was agreed that the removal or exclusion of HSS could fragment or act against the desired transdisciplinarity since it would create barriers to the production of knowledge and divide academic areas instead of providing a channel of communication between the various ways of producing research[11].

POSSIBILITIES AND CHALLENGES

In order to elicit possible alternatives to the addressed problems and resolve significant setbacks and difficulties that impair inter-pragmatic dialogue in health research, we recommend the following: **1)** The adaptation of the CEP-CONEP system and its resolutions to suit the needs of areas of HSS with the purpose of constructing a more inclusive ethics review model for these research projects;**2)** The updating of the resolution with social participation through public consultation, which means acknowledging that the review of the Resolution 196/1996, when converted to 466/2012, fell short of the aspirations and needs of much of the scientific community; **3)** The CEP-CONEP system should foster the creation of CEPs dedicated to HSS research projects and the permanent training of the members of this system; **4)** Greater involvement of people from areas of HSS in the CEPs and the encouragement of access of these individuals to the CEPs together with the progressive training of its members in the methods and techniques used in these areas; **5)** Investments in the training and development of researchers to elaborate the bioethical arguments of their projects; **6)** The building of awareness of the CEP-CONEP members who review research in the HSS. The CEP must use its multi-professional potential to carry out its functions and adopt a transdisciplinary approach in the plenary discussions and ethical reviews of projects; **7)** Continuous investments in training for reviewers and representatives of the users.

It is also essential to increase the number of CEPs and ensure that they increase the quality and resolvability of their activities. The CEP-CONEP system itself needs to create alternatives that encourage attendance and permanence in the meetings, and the efficiency of volunteer reviewers. Alternatives to these limitations would be, for example, the calculation of work hours at the CEPs as being actual work hours at the institution; curricular and institutional recognition of the work at the CEPs as a criterion for career promotion and promotion in other systems of scientific merit[11].

FINAL CONSIDERATIONS

Despite the approval of the new resolution and publication of the specific draft for HSS, researchers are still

facing difficulties and problems, especially in these areas of knowledge, regarding the ethical review procedures for human research. In the medium term, the new revision of the draft submitted in 2014 is expected to resolve such problems. A workgroup of the HSS/CONEP should continue working on the draft regarding these areas of knowledge and encourage a paradigm shift in ethical judgements under the auspices of specific guidelines. Such an advancement depends on effective dialogue that, in turn, requires the establishment of non-hierarchical relations, the acknowledgement of diversity, shared management and, above all, respect for differences.

Moreover, the ethical review of research involving humans, when based on appropriate criteria and managed by a system of standards with a satisfactory operational capability and insofar as different research traditions and their specific characteristics are considered, can achieve the primary objective of protecting the fundamental interests of research participants while guaranteeing their safety, dignity and well-being. Researchers must fundamentally employ continuous ethical practices in research so that the CEPs do not become an obstacle, but a support mechanism for the achievement of the highest ethical standards.

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