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Alves Rippel, Jessica; Alvarenga de Medeiros, Cleber; Maluf, Fabiano
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Universal Declaration on Bioethics and Human Rights and CNS Resolution 466/12: a comparative analysis

Jessica Alves Rippel[1], *Cleber Alvarenga de Medeiros*[2], *Fabiano Maluf*[3]

Abstract

This paper aims to perform a comparative analysis of Brazilian Resolution 466/12 and the Universal Declaration on Bioethics and Human Rights, in the context of research on human beings, to verify if the Resolution deals with the principles defined by the Universal Declaration on Bioethics and Human Rights. The results showed that while the Unesco text describes the ethical principles that guide the respect of human dignity, in addition to dealing with biomedical, biotechnology, sanitary, social and environmental issues, the Brazilian Resolution is still heavily influenced by clinical bioethics and focused on biomedical practices. The Resolution lacks terms such as "solidarity", "responsibility", "individual responsibility", "diversity" and "social development". The Declaration discusses the term "equity", while the Resolution deals only with "reducing inequalities". Published seven years after the signing of the Unesco Declaration, the Brazilian paper has a more principlist content than the comprehensive and political content of the Unesco document.
Keywords: Bioethics. Research, ethics. Human rights.

Resumo

***Declaração Universal sobre Bioética e Direitos Humanos* e Resolução CNS 466/2012: análise comparativa**

Este artigo objetiva realizar análise comparativa entre a Resolução 466/2012 do Conselho Nacional de Saúde e a *Declaração Universal sobre Bioética e Direitos Humanos* da Organização das Nações Unidas para a Educação, Ciências e Cultura, no contexto de pesquisas envolvendo seres humanos, para verificar se a resolução aborda os princípios preconizados pela declaração. Os resultados mostram que, enquanto o texto da declaração traz os princípios éticos do respeito à dignidade humana, além de questões biomédicas, biotecnológicas, sanitárias, sociais e ambientais, a resolução ainda é bastante influenciada pela bioética clínica e as práticas biomédicas. Observou-se ausência na resolução dos termos "solidariedade", "responsabilidade", "responsabilidade individual", "diversidade" e "desenvolvimento social". A declaração utiliza o termo "equidade", enquanto a resolução apresenta apenas "redução de desigualdades". Publicada sete anos após a assinatura da declaração, a norma brasileira possui mais conteúdo principialista do que o conteúdo abrangente e político da declaração.
Palavras-chave: Bioética. Ética em pesquisa. Direitos humanos.

Resumen

Declaración Universal sobre Bioética y Derechos Humanos y Resolución CNS 466/12: análisis comparativo

Este artículo tiene por objetivo realizar un análisis comparativo entre la Resolución 466/12 del Consejo Nacional de Salud y la Declaración Universal sobre Bioética y Derechos Humanos de la Organización de las Naciones Unidas para la Educación, la Ciencia y la Cultura en el contexto de las investigaciones que involucran seres humanos, para verificar si la resolución planeta los principios recomendados por la declaración. Los resultados muestran que, por un lado, el texto de esta organización expone los principios éticos del respeto a la dignidad humana, además de interrogantes biomédicas, biotecnológicas, sanitarias, sociales y ambientales y, por otro, la resolución aún está bastante influenciada por la bioética clínica y las prácticas biomédicas. Se observó la ausencia en la resolución de los términos "solidaridad", "responsabilidad", "responsabilidad individual", "diversidad" y "desarrollo social". La declaración utiliza el término "equidad", mientras que la resolución utiliza solo "reducción de desigualdades". Publicada siete años después de la firma de la declaración, la norma brasileña presenta más contenido principialista que el contenido abarcador y político del documento de la Unesco.
Palabras clave: Bioética. Ética en investigación. Derechos humanos.

1. Especialista jessicarippel@hotmail.com – Ministério da Saúde (MS), Brasília/DF **2. Especialista** cleber.alvarenga@gmail.com – MS **3. Doutor** maluffabiano@gmail.com – Universidade de Brasília (UnB), Brasília/DF, Brasil.

Correspondência
Jessica Alves Rippel – Condomínio Mini Chácaras do Lago Sul, quadra 6, conj. 9, casa 5 CEP 71680-621. Lago Sul/DF, Brasil.

Declaram não haver conflito de interesse.

Research articles

From Potter's bridge to the future [1] to its present plural and interdisciplinary contents, Bioethics has evolved among norms and resolutions accepted worldwide. This advance is related to the *Universal Declaration on Bioethics and Human Rights* (UDBHR), published by the United Nations Educational, Scientific and Cultural Organization (Unesco) in October, 2005 [2]. The document, which implies a change in paradigm in the concept of bioethics, states the need to consider, in an analogous way, political and social aspects besides the aspects of life sciences already addressed.

Proclaimed unanimously by the UNESCO General Conference, at the 33rd session in Paris, the UDBHR changes the focus on the area of science and technology in addressing ethical issues related to medicine, life sciences and applications of technology related to humans, by considering the social, legal and environmental dimensions [3]. The declaration aims to provide a universal framework of principles and procedures to guide States in formulating their laws, policies or other instruments in the field of bioethics [2]. To that end, it is guided by international laws on human rights, considering the respect for human dignity and fundamental freedoms as essential to the development of the bioethical principles presented in them.

In Brazil, the clinical study had its first official document, which regulates health research standards, published on June 13, 1988. Resolution 1 of the National Health Council (Conselho Nacional de Saúde, CNS), later replaced by Resolution 196/1996. This and other complementary resolutions, also approved by the CNS, establishes fundamental ethical and scientific requirements to guarantee the rights of research subjects. Whereas all research involves risks, be them physical or psychological, individual or collective, it was determined that there should be control for the preservation of physical, mental and social health of those involved. Thus, it was established that all research involving humans should be approved, prior to being started, by a Research Ethics Committee (Comitê de Ética em Pesquisa, CEP) and/or the National Research Ethics Commission (Comissão Nacional de Ética em Pesquisa, CONEP), the CEP-CONEP system [4].

CNS resolutions are not statutes, laws or self-administered notary provisions, but rather instruments of an ethical essence to build the conditions for evaluation of research protocols, requiring judgment values and case analysis, taking the dignity of the human being as a guideline [5]. In this sense, according to Guerriero and Minayo [6], the rules on ethics in research involving humans synthesize what a particular society considers right and fair to guide the behavior of researchers in a given historical moment. The discussion on research ethics and regulation is therefore political and always revisable. The challenge is to set ethical guidelines applicable to various scientific communities, both in terms of principles as procedures [7].

In Brazil and in the world, many documents were designed to address guidelines for research involving human subjects in different contexts, in particular, and especially in the biomedical field. After public consultations held in 2011, Resolution CNS 466/2012 [8] revoked Resolution CNS 196/1996 and currently guides the performance of this type of study.

Analysis of the two documents – the UDBHR and CNS Resolution 466/2012 – reveals significant differences in their approaches. The Unesco text brings a more comprehensive and political bioethics, enshrines the principles and values of human rights, and brings innovative concerns in its scope - for example, the environment and social inequalities. The Brazilian resolution is still heavily influenced by a clinical bioethics, focused on biomedical practices.

The issues that led to this study emerged from the reflection on the development of guidelines for ethics committees in Brazilian research and considered what was proposed and ratified in the UDBHR. The issue gains in consistency as one realizes that CNS Resolution 466/2012, published seven years after the signing of the UDBHR, presents a more principialist content than the Unesco declaration.

Attentive to the precepts worked for global bioethics, and having the UDBHR as a world reference to aid the relevant legislation for each country, the purpose of this article is: 1) to discuss whether the principles suggested in the declaration are considered in creating resolutions; 2) to perform comparison between these two documents; and 3) to check how the current resolution addresses the principles advocated by the statement.

Methods

As an exploratory and descriptive study, this research formulated a reference framework, linking and comparing theoretical proposals, concepts and hermeneutic dimension between two documents: one national, CNS Resolution 466/2012, and the other, international, the UDBHR. The comparative

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analysis took the principles of UDBHR as reference for discussion beyond the principialist approach, particularly in what concerns human rights. By associating bioethics as a particular normative field in the attention and care for life and health, with human rights as a basic universal normative field of moral and legal obligations to all forms of human life, core values of a sustained universal ethics for human dignity, equal rights, freedom, justice, brotherhood and peace are identified [9].

For Garrafa [10], the UDBHR is an international agreement that aims to group ethical principles guiding the respect for human dignity, not only related to biomedical and biotechnological issues, but also to health, social, and environmental issues; aspects of great interest to poor or developing nations.

The statement appears as a new ethical framework, which allows the use of guiding frameworks of action in a critical, anti-hegemonic, socially engaged and politically committed perspective. The publication of the UDBHR confirms the importance of bioethics as a tool to assist in the resolution of ethical conflicts that go against human rights.

Initially, the full contents of both documents were investigated. To facilitate the analysis, the whole UDBHR was previously arranged in a table, being divided by its articles. Each UDBHR article was sought in the CNS Resolution 466/2012 to find differences and similarities between the documents. The articles, paragraphs and texts identified in the resolution were inserted into the table for better identification, visualization and comparison of themes. Subsequently, a new reading, adapted to plain text, was carried out to identify similarities between the two documents in order to meet the goal of the present study.

Results

According to Novoa [11], CNS Resolution 466/2012, divided in thirteen parts, appears longer and more philosophical than its predecessor. In its scope, it has the basic references of bioethics, such as the recognition and affirmation of dignity, freedom, autonomy, beneficence, non-maleficence, justice and equity, among other rights and duties regarding research participants and the scientific community [8]. According to the same author [11], CNS Resolution 466/2012 is not a code of strict rules, but provides guidelines that lead the ethical judgment of the protocols and establishes operational standards used by the scientific and academic communities. It will always be under evaluation in order to identify possible improvements in future updates.

In this sense, Porto and collaborators [12] denounce the relaxation of ethical control standards in research involving human subjects identified in the current resolution, grouping them into five main areas, which will be analyzed later: 1) suppression of the control by the CEP-CONEP system on international clinical trials; 2) removal of the need for approval of international research by the country of origin; 3) removal of the obligation to suspend the trial on suspicion of injury or damage and providing the benefits of the best regime; 4) non-preventive use of the protocol of data and/or biological material; and 5) remuneration of participants in phase 1 clinical trial and in bio-equivalence research.

With a comprehensive preamble and 28 articles, the UDBHR proposes a broad definition of bioethics to include social responsibility of governments in terms of health and collective well-being, environmental preservation and cultural diversity, as well as recommendations that call for the fight against poverty and social exclusion [12]. Although not specifically designed for scientific research, the declaration addresses various aspects related to the protection of human research participants along with the social, health and environmental issues that so devastate vulnerable nations.

The statement also proposes four items for application of the principles as well as four others for their promotion through the actions of States; information, training and education in bioethics; international cooperation; and monitoring by UNESCO. The Following is a comparative analysis between the two documents with the respective item of the resolution in parentheses.

Article 3: Human Dignity and Human Rights

Recommends respect to human dignity, human rights and the fundamental liberties in all their aspects.

CNS Resolution 466/2012 – In its preamble, it dedicates special attention to the protection of participants in scientific research, recognizes the *Nüremberg Code* and the *Universal Declaration of Human Rights* as pillars of dignity, it also mentions the established codes of bioethics - such as the very UDBHR - and makes values of the Constitution explicit. It establishes a link between dignity and informed consent (III.1.a, IV and IV.6.c.3).

For Bergel, *the defense of human dignity before the pitfalls of a world that advances precipitously,*

leaving out large masses of the population which remain trapped through their dramatic exclusion from the most diverse areas of life, establishes the inextricable link between bioethics and human rights. Including human rights among its principles, the UDBHR *incorporated human rights issues relating to the social and economic conditions of human life and health,* recognizing the social dimension as intrinsic to bioethics [13].

Article 4: Benefits and Harm

This article mentions research subjects for the first time, but it is not restricted to them in the extent of benefits and damages. It includes possibly affected individuals. To these two groups, any possible damage must be minimized, and benefits must be maximized when it comes to advancing scientific knowledge, medical practice and associated technologies.

CNS Resolution 466/2012 – In this item it is necessary to separate the benefits and damages, since they present specific concepts along the resolution, with a different approach than the one of the international document. The articles are basically limited to the principles of beneficence and non-malevolence.

- ***Harm***

The resolution brings a broad definition of harm and explicit criteria for prevention and repair (II.3.2, II.6 and II.22). It emphasizes the importance of considering risks and benefits (III.1.b) and the prevention of avoidable harm (III.1.c), both characteristics defined by the principles of beneficence and non-maleficence, respectively. Care for women of childbearing age is highlighted, so that their fertility is not impaired (III.2.r). Justifies the use of placebo in studies where there are no proven methods of prevention, diagnosis or treatment, confirming the need for comparison of new therapeutic method in a study of the best current prophylactic, diagnostic and therapeutic methods (III.3.b).

Protection to research participants is added, bringing guarantee of compensation for possible damages, predicted or not (V.7) and obligation to include in the free informed consent (IC) the details of the discomforts and risks, expected benefits and procedures to avoid damage for greater clarification of the participant (IV.3.b). The protection is extended by stressing that participants must not give up their rights to compensation for possible damage (IV.3.h and IV.4.c). The CONEP is stated as an institution that should monitor risks and damages and to which risks or significant damage shall be communicated to protect the participants. It further recommends immediate and comprehensive assistance to participants if there are complications and damage resulting from the research (V.6).

However, as Porto and collaborators highlight, *by the current version of the document, the researcher is not required to immediately suspend the study, only to evaluate it on an emergency basis, verifying the need to adapt or suspend the test, ie, allows for the removal of the requirement of test suspension for suspected risk or damage and immediate provision of the benefits of the best regime* (V.3 and V.4) [14].

- ***Benefits***

The resolution brings a comprehensive definition of the benefits of research (II.4). It emphasizes that the importance of the benefits of the study are felt by study participants after its completion (II.2.l, II.2.n and III.3.d) and explains the items that account for the participant (IV.3.c). Admits only indirect benefits to research participants in the topic "Of risks and benefits" (V.2).

Paranhos and collaborators [15] support article 4 of the UDBHR as a reference that is *more comprehensive, more democratic in the global sense of the word, and more concerned whit the aspirations of the more vulnerable ones*, thus stressing the insufficiency of the Belmont Report [16] as an argument instrument.

Article 5: Autonomy and Individual responsibility

Provides for special measures to respect and protect the rights, decisions and interests of individuals.

CNS Resolutions 466/2012 – Considered the most important principle of principialism, the relevance of this item is present in the preamble, along with other principles in the section on the preliminary provisions and in items of the section on the ethical aspects of research involving human subjects (III.1.a). It indicates that research should preferably be carried out with fully autonomous individuals (III.2.j). In "The free and informed consent process," it deals with the importance of the clarification and understanding of the research terms so that autonomy and freedom of consent are preserved, that is, the resolution makes it clear that the consent of the research participant must be obtained via steps such as process stages (IV).

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Article 6: Consent

Any medical activity or scientific research should only be carried out with prior free and informed consent from the participant. This consent may be withdrawn at any time or for any reason, without causing disadvantage or prejudice. In case of groups or communities, consent must be given by the legal representative or leader of the community, subject to individual consent.

CNS Resolution 466/2012 – Consent is evaluated as the acquiescence of the participant or legal guardian, free of vices, dependencies, subordination or intimidation, after clear explanation of the nature of the research, its methods, objectives, benefits, risks and discomforts (II.5). The document to express such clarification is the IC, which must be written, objective and accessible to the best of the research participant's understanding (II.23).

Data and biological material collected during research must be exclusively for the purpose of the protocol or in conformity with the participant's consent. In this sense, Porto and collaborators [12] warn that the current wording allows the use of biological material and data only with the consent of the research participant and not in accordance with the provisions of IC appreciated by the CEP. It also allows the definition of the study and *a posteriori* use of biological material without the knowledge or the ethical control of the CEP-CONEP System.

The resolution has the necessary rules for the IC to take effect, with highlight to research on individuals diagnosed with brain death (IV.6.c) and care for indigenous peoples, groups and communities whose culture involves representative leadership. In the case of indigenous peoples, when the Brazilian law disposes on the competence of government agencies, there must be prior authorization of the National Indian Foundation (Fundação Nacional do Índio, Funai), subject to individual consent (IV.6.e).

Article 7: Persons Without the capacity to consent

This article ensures special protection for those who do not have the capacity to consent. The authorization to participate without capacity to consent should be obtained only if it ensures direct benefit to the individual, in accordance with national laws and if there is no comparable research alternative. Refusal to participate should be respected.

CNS Resolution 466/2012 – Innovates by introducing the consent term for minors and the legally incapable (II.24). To have consent from legally incapable, after clear justification of the choice, the steps of obtaining the informed consent must be met through their legal representatives, without, however, denying them the right information at the limit of their capacity (IV.6.a). In the case of restriction of freedom of this delicate group, there must be justification for the trial of the CEP or CONEP, as applicable (IV.6 and IV.7).

Article 8: Respect for human vulnerability and personal integrity

Ratifies the protection of individuals and groups with specific vulnerability and the respect for individual integrity. It emphasizes that vulnerability should be taken into consideration in applying and advancing the scientific development of medical practices and associated technologies.

CNS Resolution 466/2012 – Treats vulnerability as the state of people or groups that have reduced or prevented capacity of self-determination or are unable to resist, especially regarding the consent (II.25). It states that the vulnerability must be recognized for any research participant, respecting their contribution or their leaving the study (III.1.a). Vulnerable individuals or groups should not participate in research when it can be applied to participants with full autonomy, unless it brings direct benefits to the individual or group (III.2.j).

About this aspect, Porto and collaborators [12] call attention to the possibility of remuneration of participants in phase 1 clinical trials and bio-equivalence research, as stated in item II.10 of the resolution. They warn that this possibility opens a precedent for the "professionalization of human guinea pigs", especially of socially vulnerable groups, an aspect that goes radically against the respect for human vulnerability and for individual integrity advocated by the declaration.

Article 9 º: Privacy and confidentiality

Privacy and data confidentiality must be respected, and such information should not be used for purposes other than those for which they were consented.

CNS Resolution 466/2012 – Provides assurance of confidentiality and privacy (IV.3.e), and its express warranty in the IC. The resolution also provides that if the IC is harming the privacy and confidentiality of the future participant research, the document waiver should be justifiably requested the CEP-CONEP System (IV.8).

Article 10: Equality, justice and equity

The fundamental equality of all human beings in dignity and rights should be respected, so that everyone should be treated justly and equitably. The statement deals with the fundamental values of bioethics, such as dignity and human rights, autonomy and individual responsibility, consent, respect for human vulnerability and personal integrity, confidentiality, equality, justice, fairness. It also deals with issues related to prejudice and responsibility towards future generations and the environment [2], a theme that has been gradually included in the bioethics agenda**.**

CNS Resolution 466/2012 – The term "equality" is not found in the resolution. As for justice and equity, they are together in the preliminary provisions section in the enumeration of the terms of principialism (item I). The word "equality", understood as historical product in the major instruments of international human rights, just as the word "equity" is currently considered the epistemological foundation of the Organic Health Law ("Lei Orgânica da Saúde", Law 8.080 / 1990 [17]), although at first, there was reference to equality in the Federal Constitution [18], defined in article 196 as "universal and egalitarian access".

Duarte highlights the richness and complexity of the debate about equity and justice in the sanitary field. The author emphasizes that *the deepening and elaboration of conceptual constructs which can be made operational may contribute to minimize inequalities resulting from social iniquities, especially important in the less developed countries* [19].

Article 11: Non-discrimination and non-stigmatization

No one should be discriminated against or stigmatized for any reason, which constitutes a violation of human dignity, human rights and fundamental freedoms.

CNS Resolution 466/2012 – Quoting the preamble to the Constitution as well as international documents on ethics, human rights and development, it states that there should not be any form of discrimination. There is still the provision for procedures to ensure the non-stigmatization and the duty to protect the participant's image in research involving human beings. (III.2.i e III.2.m).

It is important to emphasize the contribution of bioethics in order to prevent scientific and technological advances from being at the service of stigmatizing and discriminatory practices that can to strengthen dominant social groups at the expense of less valued groups. The reference to human dignity and non-stigmatization and non-discrimination are benchmarks of decisions on policies or best practices in health and may contribute to difficult decisions [20].

For Godoi and Garrafa , the defense of personal dignity, considered as a central principle of human rights, *is imperative and requires the fight against the processes of discrimination and stigmatization, which contribute to increase the vulnerability of certain social groups. The differences and the different moralities should not be constituted as discriminatory factors* [21].

Article 12: Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be duly recognized, as long as these do not violate human dignity, human rights, fundamental liberties and other principles defined in the document.

CNS Resolution 466/2012 – The term "diversity" is not found. As for the cultural dimension, it must be considered one of the parameters to be preserved in any research. This reiterates that cultural, social, moral, religious and ethical values, as well as habits and customs, must always be respected (III.2.k). Research should also be adapted to local culture and language (IV.5.b). On pluralism, the approach is different from that of the UDBHR, the preamble focusing only on political pluralism in citing the Federal Constitution.

Article 13: Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

CNS Resolution 466/2012 – The term "solidarity" is not found in the resolution. As to the term "cooperation", in the case of foreign cooperation, commitment and advantages for research participants in Brazil must be proven (III.2.p).

In the words of Garrafa and Soares [22], the idea of solidarity manifested in the UDBHR requires another look – bilateral and reciprocal – among people, groups or sectors in different historical-social situations, whose emphasis is the one expressed in the conception of human rights. *For this perspective, some are trained to support others altruistically,*

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with no concern for material gain or gain of any other nature [22].

Article 14: Social responsibility and health

The promotion of health and social development is a central goal of governments, shared by all sectors of society. The UDBHR considers the highest standard of health that can be reached as a fundamental right, implying access to quality health care and essential medicines, adequate nutrition, improved living conditions and the environment, elimination of marginalization and exclusion of individuals and reduction of poverty and illiteracy, without distinction or discrimination.

CNS Resolution 466/2012 – The terms "responsibility" and "social development" are not found. According to the national document, research ethics is intimately associated to its social relevance and its social-humanitarian destination (III.1.d).

Article 15: Sharing of benefits

Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.

CNS Resolution 466/2012 – Ratifies the benefits from the study for survey participants, in terms of social return or access to procedures, products or research agents (III.2.n). It also assures them free and indefinite access to the best proven prophylactic, diagnostic and therapeutic methods that have proved effective (III.3.d).

Article 20: Risk assessment and management

Promotion of the evaluation and proper management of related medical risk to life sciences and associated technologies.

CNS Resolution 466/2012 – Research with humans involves different types and varied degrees of risk (XIII.6). Possibilities of immediate or later harm, be it direct or indirect, on the individual and collective levels must be considered. It also determines that risk analysis is an indispensable component of ethical analysis, giving origin to the monitoring plan that must be offered by the CEP-CONEP system in each specific case (II.6 e V).

The current wording increases the risk of sending biological material abroad only with the consent of the research participant, without any control of the CEP-CONEP system, as pointed out in this paper in the discussion of Article 6 of the Resolution [12].

Article 21: Transnational practices

When the study is conducted in one or more States and funded by a different one, both the Host State and the Donor State should promote careful ethical analyses. This review should be based on ethical and legal standards consistent with the principles set out in the UDBHR. When transnational research is relevant to the health sector, it must meet the needs of the host countries and must have recognized importance in contributing to the reduction of urgent global health problems.

CNS Resolution 466/2012 – Allows for the development of research abroad or with foreign cooperation (III.2.p). Here the concern turns to the suppression of control by the CEP-CONEP System through the task of examining the ethical aspects of international clinical trials.

Porto and collaborators [12] share the concern when analyzing two added restrictions which strongly affect the exercise of social control. The first one, in item IX.4.1.1, *except in cases in which there is cooperation with the Brazilian Government* [8], allows the researcher to decide about sending genetic material abroad without consultation to the CEP-CONEP System or any previous control.

The second one, in item IX.4.8, e*xcept for those co-sponsored by the Brazilian Government* [8], permits the performance, in Brazil, of international studies without any examination by the CEP-CONEP System. The authors highlight that Brazilian researchers and institutions have been working in foreign research projects, with the task to recruit and apply protocols developed in other countries which were previously examined by the CEP and CONEP [12]. It also reiterates that the assessment of research with priority on themes of public relevance and strategic interest of the priority agenda for the Brazilian Unified Health System, (Sistema Único de Saúde, SUS) (VIII.1) and that the ethical specificity of these research projects will be covered in a complementary specific resolution (XIII.4).

Article 24: International cooperation

States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in

generating and sharing scientific knowledge, the related know-how and the resulting benefits.

CNS Resolution 466/2012 – Determines technical cooperation and accessibility to studies of countries that participate in cooperation with Brazil, responding to knowledge and technology transfer needs for the Brazilian team (III.2.p). However, it does not require prior ethical review and approval of the research project in the country of origin, establishing the possibility of ethical double standards in international clinical studies which may therefore violate the participants of the research [12].

According to Santana and Garrafa [23], the interpretation of this a UDBHR article very clear about the responsibility of States in international cooperation toward the solidary sharing of technical and scientific development and theirs benefits in terms of wealth and well being, *whose projection in the political-institutional domain may contribute to the reduction of inequalities in health conditions among nations.*

Discussion

Systematic analysis shows that CNS Resolution 466/2012 has some issues due to the relaxation of control standards, even when compared to its predecessor, the 196/1996. No details of the composition of the CEP and CONEP or their attributions and detailed field of action, which, according to the document itself, will be the object of additional regulation [12]. Similarly, it makes no mention of the broad social representation, supported by SUS, does not specify the form of organization, the mandate, the mechanisms of selection of members and methods for file maintenance.

In this sense, CNS Resolution 466/2012 has points to be improved, but it is fundamental to keep the independence of the CEP and their ethical analyses, as well as the integrity of research participants. On the other hand, UDBHR articles place bioethics within the human social reality and open new perspectives for reflection and action. While the declaration is not binding in itself, it is intended to provide guidance for the development of national laws and professional regulations in the decisions to be taken or practices to be developed by those to whom it is addressed [3].

According to Saada [24], the technical and scientific advances that characterize the current world impact on human behavior, both individual and collective, on interpersonal relationships, moral and ethical values that govern and regulate social life. The set of UDBHR articles seek to contemplate the list of conditions that have such impact in order to objectively respond to demands for ethical solutions to problems arising from these changes.

In comparison, the absence of terms such as "solidarity", "responsibility", "individual responsibility", "diversity" and "social development" in the resolution is remarkable. It is also remarkable that the UDBHR includes the term "equity", while the resolution only mentions "reducing inequalities". The term "dignity" is widely exploited by both documents, being more scrutinized in the declaration. In the Brazilian standard, the word "vulnerable" receives little attention, although the research participant is the weakest link of clinical research. Relegating many relevant principles in its text puts the resolution itself, as well as research participants, in a vulnerable situation. The term "vulnerability" appears only as a definition when determining that research should not be made in vulnerable groups, unless there is no alternative.

Despite the mention to the UDBHR in its preamble, the wording of CNS Resolution 466/2012 is very technical, but little politicized and based on the principialist bioethics. At the occasion of the change of policy about research with human beings - from 196/1996 to 466/2012 –, the Unesco declaration had been ready for seven years. It was expected that Brazil changed its theoretical references, but the ideological content was maintained with strong influence of Beauchamp and Childress [25], despite the Unesco Declaration and the *protection bioethics* and the *bioethics of intervention* developed in the country.

Principialism recognizes it may not always be possible to respect the four basic principles due to occasional conflicts among them, and therefore can not have simple, one-sided application, on the risk of losing their moderating effectiveness. These are, no doubt, important reference ordering arguments for ethical analysis on the moral conflicts, but their incorporation and assimilation are not enough without their adaptation to the specific cultural realities [26].

Thus, we infer that a stronger presence of the UDBHR in the resolution would provide more suitable conditions for the evaluation of research projects, would bring more security to the volunteers of research and could, without constraints and within normality, better ordain and prevent possible abuses and coercions [27].

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Final considerations

CNS Resolution 466/2012 has a focus: research involving human beings conducted in the Brazilian territory. Its rules are linked to the daily practice of health professionals and restricted to the principialist conduct. Of course, autonomy, benefit and harm are widely discussed in the resolution, but the term "justice" appears only twice in the text: in its preamble and in relation to the analysis of protocols by the CONEP. In the resolution, the application of the terms is detailed as a procedure for research involving human subjects in the biomedical area.

The UDBHR proposes broader and more politically and socially inclusive action. Its wording bring broad, general ideas, for broader applicability and scope. It is appropriate to emphasize the binding nature of the Brazilian standard as a remarkable difference between the two documents, despite not being a law, and also the non-binding character of the declaration, as well as the fact that one of them is an internal document and the other is international.

Despite the number of existing statements, regulations, treaties and agreements, there are still many reports of abuses in clinical research, including in Brazil. Thus, it is expected that the individual who is submitted to research, usually in strong need for its resources and medicines, be better supported by the country's standards. The resolution could better serve this audience with the concepts brought by the UDBHR. In a vast and plural country such as Brazil, the influence of UDBHR contributes to the discussion from potential population inequalities scenarios, a plurality of values and culture, as the scope of the resolution misses items such as illiteracy and social exclusion.

The UDBHR brings principles which are not rules, but points for reflection on which legislation, as well as ethics and resolutions codes should be based. However, the faint presence of the UDBHR in the resolution has no support or justification when the best ethical conditions should be considered. The declaration guarantees the dignity and other human rights for participants of research and clinical trials, especially in contexts where there is social vulnerability of extreme importance.

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Research articles

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