Revista Bioética
Print version ISSN 1983-8042 On-line version ISSN 1983-8034
Rev. Bioét. vol.26 no.4 Brasília Oct/Dec. 2018
Doi: 10.1590/1983-80422018264267

UPDATE

Bioethics: criticism of principialism, Brazilian Constitution and principle of human dignity

Antônio Macena Figueiredo [1]

---

1. Universidade Federal Fluminense (UFF), Rio de Janeiro/RJ, Brasil.

Abstract

The insufficiency of the theoretical model of bioethics proposed by Tom L. Beauchamp and James F. Childress for regulating biomedical research has long been discussed. Nowadays technological interventions that manipulate human life are increasingly requiring new ways to protect the dignity of people submitted to scientific experiments. This article aims to demonstrate the relevance of the principle of dignity to regulate biomedical researchs involving human beings. The study demonstrated the insufficiency of the principialist as the main model to apply to research involving human beings in the biomedical area The relevance of the principle of dignity as a paradigm for conducting scientific experiments involving human beings was evidenced through the analysis of the axiological framework of international bioethics, constitutional rights and guarantees, infraconstitutional laws ande legal doctrine.

Keywords: Bioethics. Constitution and bylaws-Brazil. Biomedical research. Humans. Morals.

Resumo

Bioética: crítica ao principialismo, Constituição brasileira e princípio da dignidade humana

Há muito se discute a insuficiência do modelo teórico da bioética proposto por Tom L. Beauchamp e James F. Childress para regular pesquisas na área biomédica. No entanto, nos dias atuais as intervenções tecnológicas manipuladoras da vida humana necessitam cada vez mais de novas formas de tutelar a dignidade das pessoas submetidas a experiências científicas. Dessa forma, este artigo teve por objetivo demonstrar a pertinência do princípio da dignidade para regular pesquisas biomédicas envolvendo seres humanos. Além disso, o estudo demonstrou a insuficiência da corrente principialista como conceito-matriz aplicado a pesquisas com seres humanos na área em questão. A partir da análise do marco axiológico da bioética internacional, direitos e garantias constitucionais e de legislação infraconstitucional e doutrinária, evidenciou-se a pertinência do princípio da dignidade como paradigma para conduzir experimentações científicas com pessoas.

Palavras-chave: Bioética. Constituição e estatutos-Brasil. Pesquisa biomédica. Seres humanos. Princípios morais.

Resumen

Bioética: crítica al principialismo, Constitución Brasileña y principio de la dignidad humana

Hace tiempo que se discute la insuficiencia del modelo teórico de la bioética propuesto por Tom L. Beauchamp y James F. Childress para regular las investigaciones en el área biomédica. No obstante, en los días actuales las intervenciones tecnológicas manipuladoras de la vida humana vienen requiriendo cada vez más nuevas formas de proteger la dignidad de las personas sometidas a las experiencias científicas. El presente artículo tiene como objetivo demostrar la pertinencia del principio de la dignidad para regular las investigaciones biomédicas que involucran a seres humanos. El estudio demostró la insuficiencia de la corriente principialista como principio matriz aplicado a las investigaciones que involucran a seres humanos en el área biomédica. A partir del análisis del marco axiológico de la bioética internacional, de los derechos y garantías constitucionales, de las legislaciones infraconstitucionales y doctrinales, se evidenció la pertinencia del principio de la dignidad como paradigma para la conducción de las experimentaciones científicas que involucran a seres humanos.

Palabras clave: Bioética. Constitución y estatutos-Brasil. Investigación biomédica. Seres humanos. Principios morales.

Declaram não haver conflito de interesse.

The work of the American oncologist Van Rensselaer Potter[1], "*Bioethics: bridge to the future*", published in 1971, is recognized as a historical reference for the emergence of the neologism "bioethics". However, the first theoretical reference to bioethics began to be built from the creation of the Kennedy Institute of Ethics, the world's first institute dedicated to the theme[2,3], whose members came to conceive the term as ethics applied to moral issues in biomedical research[4].

Researchers were concerned about the ethical limits of human research, as two particular cases were mobilizing the North-American public opinion[5]: the study published by Henry K. Beecher[6] in The New England Journal of Medicine in 1966, about studies on people incapable of expressing their will; and the famous Tuskegee case of 1972, which, in order to monitor the evolution of syphilis, omitted the diagnosis and its consequences from the participants, poor people left untreated[7].

This repercussion resulted in the decision of the US Congress in 1974 to establish a national commission to *identify the basic ethical principles that should guide human investigations in behavioral sciences and biomedicine*[8]. After four years the *Belmont Report*[9] was published, which defined ethical principles to be applied in research involving human beings: respect for people, beneficence and justice. These principles were chosen because they belonged to the moral traditions of the West, and were already implicated in many codes and norms related to research ethics[3,10].

Based on these principles, philosopher Tom L. Beauchamp and theologian James F. Childress presented the first reference book, "*Principles of biomedical ethics*", in 1979, renaming respect for people as "autonomy" and adding the principle of "non-maleficence"[11]. In the introduction to the book, the authors explain that these principles should be applied to moral problems in the medical healthcare practice[11]. In the introduction to the Brazilian edition published in 2002, Leo Pessini[12] states that with the "system of principles ", Beauchamp and Childress sought to get rid of the old ethical approach characteristic of codes and oaths. It is noteworthy that *since the 1960s scientists began to realize that the old* [Hippocratic] *tradition of medical ethics was too fragile to meet the challenges posed by the new medical science*[13].

However, there are those who consider that bioethics was born even before the disclosure of their name, since it was during the Nüremberg process in 1946 that the first ethical barriers arose[14]. As a result of the judgment of researchers who had experimented with people in serious situation of individual and social vulnerability, the *Nüremberg Code* was created. For the first time an international document was drawn up in the field of biomedical research from a humanistic perspective, whose violation came to be considered a conduct against humanity[15].

Following the *Universal Declaration on Human Rights* (UDHR)[16], of 1948, these two documents inaugurated the process of recognition of the human being as a subject of law, integrating human dignity and citizenship among the achievements of humanity. However, researchers' reluctance in subsequent years to accept the rules of the *Nüremberg Code* as the normative ethical standard for conducting biomedical research led the World Medical Association to draw up a code, adopted in 1964, known as the *Helsinki Declaration* and which had the purpose of guiding physicians involved in research[17].

Just as over the years the changes in this document began to undermine its moral validity, the claims of Beauchamp and Childress went far beyond the proposal of the *Belmont Report*, since normative matrices based on the principle of human dignity in the various international documents were disregarded. In fact, the doctrine of human rights, the primary source of universal human values, gave rise to a moral rule derived from the ancient hippocratic tradition.

Not without reason, other alternative analytic models emerged immediately, such as liberalism, virtues, casuistic, care, personalism, contractual, hermeneutics and libertarianism[3,18], as well as other international trends based on human rights. As Fabriz[19] emphasized, all these currents are important, since the dimensions of morality can not be established by just one perspective.

From the 1980s, principlism became widespread in Europe[20], becoming known throughout the world in the early 1990s[14], when it reached the countries of Latin America. It became a major influence, especially in Brazil, on health researchers and, finally, it was incorporated as an ethical reference for the social control of researches with human beings by the Research Ethics Committees (REC) and by the Comissão Nacional de Ética em Pesquisa – Conep (National Commission of Ethics in Research) in the same decade[21].

In spite of the intensification of the criticisms formulated by bioethics researchers, the insufficient moral validity of this theoretical conception is debated to date[4]. In the face of this impasse, the present study aims to demonstrate the relevance of the principle of the dignity of the human person to control research with individuals, in view of the paradigm change on ethics in studies replacing the current framework governed by administrative resolution[22].

The main criticisms formulated by two groups of bioethics scholars will be presented: first, those coming from US authors[23-27] and, second, from bioethicists of European and Latin American origin[28-33]. Then the central principles of international and national bioethics will be presented based on the principle of human dignity in the light of the Constitution of the Federative Republic of Brazil, national doctrine and legislation.

Criticism of principlism

Criticism by US scholars

The more structured criticism of Beauchamp and Childress's proposal have been made by Clouser and Gert[23], who classify the prima facie principles as a kind of mantra, something exhaustively repeated: "beneficence, not maleficence, autonomy, and justice". They affirm that it would be impossible, from their automatic or mechanical application, to solve all the ethical dilemmas in the biomedical field, since, in their view, *the principles do not function either as adequate substitutes for moral theories, nor as guiding directives or guides of moral action*[34]. For them, principlism would be a kind of anthology of theories, *starting from short summaries of some models of ethical theories*[34].

As Holm[24] states, the principlist theory was developed from the common American morality (and, in reality, only a subset of that morality), and therefore does not reflect contexts of other societies. The author asks whether such principles would have the same content if they were employed in Denmark, India or elsewhere. In his view, this current erroneously had the claim of being a universal moral theory, without recognizing the difficulty of its application in different social contexts.

Along the same lines, Gert, Culver and Clouser[25] emphasized in the first edition of their work, published in 1997, reiterating the argument in the second edition in 2006[26], that the principlist current was disclosed as a generalist model for the whole world. They have argued that the way of making the common into the general can mask moral decisions and judgments. Moreover, these authors consider that, although Beauchamp and Childress admitted some limitations in their proposal over the years, the discussion on particular cases did not change.

Another American author who has systematically criticized this current of bioethics is the philosopher Engelhardt Jr.[27], stating that although Beauchamp and Childress claim no prima facie principles, "autonomy" is overvalued. In his work "*The foundations of bioethics*", translated into Portuguese in 1998, he renamed *o "principle of autonomy" as "principle of consent", to better indicate that what is at stake is not some value possessed by autonomy or freedom, but the recognition that secular moral authority derives from the consent of those involved in a common enterprise*[35].

Thus, the principle of autonomy is based on the application of the so-called "terms of informed consent"[20]. This means that people should be object of research only by consent, and this deliberation is personal and therefore centered on the morality in the principlist view[3]. This finding is not evidenced in the application of the principle of beneficence, since it does not require the consent of the research participant for each intervention. It is in this sense that this principle is not as basic as that which Engelhardt called the principle of permission or of consent[3,36].

Taking the argument ahead, one can say that the conflicts generated between respecting patients' freedom (autonomy) and doing what is best for them (beneficence) can be said to be irreconcilable. This is because, on the one hand, people have the right to decide according to their convictions and, on the other hand, it is the duty of the professional to always think about their best interests[25]. This fact further reinforces the primacy of the principle of autonomy over medical paternalism in this philosophical current of bioethics.

However, the emergence of the principlist bioethical school in the late 1970s was not a decisive milestone for the emergence of the notion of autonomy. In fact, *the subject of respect for self-determination of the patient had already been developed in the judicial scope of the United States since the beginning of the 20th century. (...) It is even observed that the term 'informed consent' was created in the United States judicial context in the year 1957*[37]. It follows that the doctrine of free and informed consent, more than that notion emanated solely from bioethical reflection, was established as a basilar argument by American jurisprudence throughout the last century.

The decision taken as a precursor to the recognition of the patient's self-determination was given by the New York Court in 1914: *Every human being of an adult age and mentally capable* *has the right to determine what will be done in his own body*[38]. Thus, if the principle of autonomy in bioethics owes its philosophical heritage to Kant and John Stuart Mill[12], who synthesized this notion in the symbolic dimension of the West, its historicity in the biomedical field was established by the jurisprudence of the American courts, in the context of responsibility in medical practice, arising from therapeutic interventions performed without the consent of the patient[39].

Criticism by European and Latin-American scholars

The criticisms of scholars of European and Latin American origin do not depart from these questions. Campbell[28], of the University of Bristol, reinforces the criticism, given the universalistic international dimension of principlist bioethics. Although he understands that there is no obstacle to the free exchange of ideas, he points to two fundamental problems. First, the political, religious and dogmatic intolerance of each country, which makes it difficult to deal with all these particular issues with the syllogism of global ethics[3]. Second, bioethical "colonialism" would be pretentious because it believes that a certain theoretical model based on principles is conceived as universal and capable of addressing all existing bioethical problems in another country.

On the other hand, Neves emphasizes that Anglo-American theoretical models of analysis have never been well accepted in continental Europe[29]. In Portugal, besides experimentation on humans being regulated by a specific law[40], this current *is contested for outlining a general orientation, more individualistic in view of the privilege given to the autonomy of the singular person*[41].

Tealdi[30], of the National University of La Plata, in Argentina, is part of the group of Latin American scholars of bioethics and maintains that the four principles would be a kind of ethical pragmatism, since they play the role of ethical justification. It was imagined that from the application of the principlist "mantra", it would be possible to arrive, through the practical syllogism, to the establishment of moral judgments for concrete cases.

This is the reason why the model by Beauchamp and Childress *has not been accepted worldwide* [being more accepted in English-speaking countries]*, thus, it should not have been converted in an apparent letter of triumph of a moral imperialism by the Food and Drugs Administration and other regulatory bodies of research in the United States*[42], as occurred in Brazil, as it became the only ethical reference in studies with human beings since 1996[21].

Among other Latin American bioethicists, the criticisms of Miguel Kottow[31] stand out. The author states that the principlist current is far from being clarified as a theory of moral knowledge, since Beauchamp and Childress constructed their referential from theories inherited from different historical traditions. He argues that *none of Georgetown's four principles is unique to bioethics, as we conclude after 30 years of debate. On the contrary, such general ethical proposals could be introduced in the discourses of any applied ethics*[43].

An unpublished study recently carried out by Azambuja and Garrafa[32] has confirmed the pertinence of all the criticism presented so far. These authors analyzed the changes introduced in the last four editions (fourth, fifth, sixth and seventh) of the book "*Principles of biomedical ethics*". This study showed that the fourth edition *was the first to approach the theme of common morality and its theory, in an attempt to provide an answer to the numerous criticisms received*[44]. This is the first evidence of the fragility of the proposal by Beauchamp and Childress.

In the fifth edition, Beauchamp and Childress referred to principlism as a moral philosophy and not as theory. In contrast, in the sixth edition they again defended the theory of common morality in the conception of Clouser and Gert, as well as its use as a valid concept. And finally, in the latest edition, they still recognized the importance of the sixth edition, but clarifying that they were still attentive to criticism, including those of Gert himself, and willing to alter the work.

In view of this, the fragility of the theoretical foundation of this current of thought is evident, since its use as a tool of analysis fluctuates in function of the criticism it receives. If it is true that no approach to ideas related to behavior and morality can claim to arrive at the absolute, especially in relation "space" and "time", for any area of specialized knowledge to develop and reach recognition in the theoretical dimension it must have minimum consensus. That is, it must establish a more concrete field of theoretical domain, deriving or at least not contradicting notions socially accepted by common sense in the matter.

The importance of anchoring philosophical rationality in socially shared perception and values at a given time and place (common sense) is directly related to the introjection of those same principles by the social environment and its applicability in everyday life. In continental Europe, for example, the appeal to "rights" in general, and to "human rights" in particular, had greater influence than ethical principles [45] (preponderant in the American context) precisely because of its supremacy as a reference of bioethics built in that context. It can even be suggested that the position of these concepts in the European social imaginary points to the broad impact that the emergence of the notion of rights brought to the political and social order of the continent in the eighteenth century.

The growing need for the health area to respond adequately to the conflicts and dilemmas emanating from pluralistic societies, whether in the practice of care, in clinical practice, and especially in the field of research ethics, perpetuates reflections, debates and discussions on the morality of interventions in humans. Studies and scientific experiments are being carried out on the frontier of what we conceive as humanity, both in the biological, genetic and bacteriological dimension, and in robotics. Specifically, it can be said that the social control of clinical research with human beings is not only involved in moral, ethical, philosophical, economic issues, but also in serious juridical and social problems.

Hence, the space and the need to broaden the debate to overcome the excessive flexibility of the application of the principles "made in the USA", in the sense that conducting research with men and women be governed by the source principle of the right of peoples, because it is at the center of the doctrine of human rights and represent the ultimate foundation of democratic states of law - human dignity.

In summary, the historicity of the narrated facts indicates that the theoretical model proposed by Beauchamp and Childress brought together a set of moral references from various historical traditions to be applied to dilemmas within the biomedical sciences, replacing the old Hippocratic deontological tradition. However, in view of the criticism presented, it would not be unreasonable to consider that the only consensus is to reject the universal use of the principlist bioethical paradigm in regard to the very moral diversity of contemporary societies.

Human dignity: matrix-principle of international bioethics

In the field of research ethics, the need to establish global ethical-legal norms to protect the rights of individuals as a result of abuses committed in the name of scientific progress is emphasized. Considering that biomedical activities deal with the most basic human prerogatives, such as respect for life, physical and mental integrity, it is perfectly recommendable to resort to international human rights standards to guarantee this protection [46].

The debate on the creation of bioethical matrices is inserted in this context. In this section, it is based on the principle of human dignity as the axiological framework of international bioethics based on human rights [47]. Among the various possibilities of international bioethics, according to Campbell, *the first* [step] *would be to seek international codes and conventions as a way of guaranteeing high standards in biomedicine and biological sciences throughout the world* [48].

In fact, the first bioethics-related matrices in this area of research have been approached from the perspective of human rights, whose nuclear base is based on the principle of dignity. In that sense, significant progress has already been made since the publication of the *Nüremberg Code* [49], the UDHR [16] and the *Helsinki Declaration* [50] because of the historical legacies of criminal practices involving investigations of persons in situations of severe vulnerability [28,51].

These declarations of rights came to represent in the West a significant milestone in moral progress, becoming a kind of Magna Carta in defense of the dignity intrinsic to any individual [52]. For the first time, the right to one's own body was established against the interests the State, science and researchers.

Other documents share these prerogatives: the *International Covenant on Civil and Political Rights of the United Nations* (UN) [53]; the *American Convention on Human Rights - Pact of San José, Costa Rica* [54]; the *International Ethical Guidelines for Biomedical Research in Humans* [55-56]; the *Council of Europe Convention on Human Rights and Biomedicine* [57]; the *Universal Declaration on the Human Genome and Human Rights* [58]; the *International Declaration on Human Genetic Data* [59]; and, lastly, the most important document in the field of bioethics, the *Universal Declaration on Bioethics and Human Rights* (UDBHR) [60], which incorporated principles and rules that guide the respect for human dignity, fundamental rights and freedoms, and ratified by the 191 member countries of the United Nations Educational, Scientific and Cultural Organization (Unesco).

It is important to highlight that, although not all of these documents are binding on the Brazilian legal system, they still guide the definition of legislation and the implementation of public policies designed to meet its recommendations. According to Andorno[51], the Council of Europe has also been playing an important role in establishing international norms in bioethics in the countries of the region. Among the principles announced, it emphasizes the supremacy of the human being over the interests of society and science.

Along the same lines, scholars from Latin America and the Caribbean, for lack of a bioethics with their own identity, have also prepared documents in this field, among which the *Buenos Aires Charter*[61], 2004, and the *Santo Domingo Declaration on Bioethics and Human Rights*[62], 2007. In the Argentinian capital, bioethics experts and health professionals from Bolivia, Brazil, Colombia, Cuba, Chile, The Dominican Republic, Mexico, Paraguay and Venezuela met in a seminar that resulted in a statement on key issues linked to bioethics and its close relationship with human rights.

Escobar[63] reports that despite the unusual development in Latin America, the bioethics model was transplanted to this region without considering the differences in such different "soils", that is, its enormous cultural heterogeneity was not taken into account. For this author, given the intense development of bioethics from the second stage in Latin America (1990-2000), several theoretical proposals have emerged that are better suited to the sociocultural problems of the countries of the Southern Hemisphere. For example, bioethics of protection and intervention, the former being understood as ethics applied to conflicts and moral dilemmas of public health, considering that these are not developed in the main model, and the second as a proposal that adopted as a framework human rights treaties because they represent a consensus among nations[64].

The unfolding of this discussion generated another international seminar, in 2007, entitled Sub-Regional Convention on Bioethics, held in Santo Domingo, Dominican Republic. This event was promoted by bioethics scholars from the countries of Latin America and the Caribbean with the support of UNESCO, and resulted in the consolidation of the *Santo Domingo Declaration on Bioethics and Human Rights*. For Gros Espiell[62], this statement should be valued, interpreted, understood and applied in relation to the UDBHR[60].

Therefore, there is a tendency for Latin American researchers to endorse bioethics proposals associated with human rights. Consensus on bioethical morality with respect to any decision that interferes with human life, health and well-being must be in line with the principle of human dignity by involving fundamental rights and guarantees enshrined in democratic constitutions.

Human dignity in the Brazilian Federal Constitution of 1988

In line with international trends, the principle of human dignity, as the core axiological of human rights, was adopted as the basic foundation of the Constitution of the Federative Republic of Brazil of 1988, as expressed in item III of articles 1 and 4[65]. In turn, its article 5 reproduces with extreme fidelity the three precepts contained in article 3 of the UDRH[16]: life, liberty and personal security.

International treaties on human rights under article 5, paragraph 3, of the Brazilian Constitution, are equivalent to constitutional amendments[65]. This is the case of the *International Covenant on Civil and Political Rights*[53] and the *American Convention on Human Rights*[54], which have come to integrate the system of norms and fundamental guarantees after Brazil became a signatory of both in 1992. Thus, it is understood that the Constitution is the first pillar of support for the principle of human dignity.

Although the constituents defined in article 1 the dignity of the human person as a fundamental principle of the Brazilian Republic, this principle is explicitly or implicitly distributed throughout the constitutional text[65]. According to Sarlet[66], this device does not denote only a positive legal norm capable of guaranteeing the fundamental rights of the citizen, but also proves to be a declaration of ethical and moral content.

If, on the one hand, the dignity of the human person is recognized as the axiological core of fundamental rights, conceived as a binding force to measure conduct that affects the person, family and community, on the other, a principle based on a supreme norm has a greater coercive value to protect the rights of research participants against acts that violate or expose them to threats and risks, to the detriment of the interests of private actors. In fact, it should be remembered that this was the regulatory framework at the time of the genesis of the principlist reflection[67].

In addition, scholars in the human and social sciences complain that principlist criteria are inappropriate for analyzing procedures in this field of knowledge. They rightly claim that the standard arose *to cover all research "involving human* *beings," although its spirit and form clearly refers to clinical and experimental research in the field of biomedicine* [68].

The critic adds that this regulatory framework was renewed, being endorsed by the Conselho Nacional de Saúde - CNS (National Health Council) in CNS Resolution 466/2012 [69], even more focused on the biomedical sciences. In fact, within REC/Conep, the norms on researches in human and social sciences were only established by Resolution CNS 510/2016 [70], after an exhaustive (and not always satisfactory) interdisciplinary discussion. It seems, therefore, to be perfectly reasonable to ask whether these references have the characteristics necessary to protect the dignity of study participants in all areas of knowledge.

There is clear evidence that only the rule of law has this rule, since human life, health and physical/mental integrity are legal rights protected by the constitutional order. As Séguin points out, *the Brazilian Constitution has elevated the protection and promotion of the human person to a maximum value of the order, stating that the dignity of man is inviolable, being a propeller of the intangibility of human life* [71]. From this, arise the respect for physical and psychic integrity, freedom, equality and the minimum assumptions for good living. In the words of Fabriz*, the manipulation of life (turning the human being into a "thing") imposes questions about the scientific advances and the responsibility of the science itself and its operators, both before the individuals submitted to the processes of experimentation and before the whole collectivity, are issues of concern to mankind in general.* [72].

The Law project 200/2015 [22], which represents a paradigm shift in the area of research ethics, is being discussed in the National Congress, because the principle of the dignity of the human person will be the new reference for conducting clinical studies with individuals in the country. That is, control would be established under the ontological view of human dignity in the light of the Constitution of 1988. Of course, it should be noted that, although any change is natural to the discussions, what should not be accepted are possible setbacks in achievements of the rights of research participants throughout the history of the REC/Conep system [73].

Oliveira [15] emphasizes that the concept of ontological dignity is that of equality, that is, the same for all, regardless of any condition. It is the value that is attributed to every person just because one exists*: the dignity of man is not linked to the valuation of the person due to his or her belonging to a particular race or social layer, but is linked to the idea of being part of humanity, as a collective of individuals, and at the same time brings within itself the humanity that characterizes the human race* [74].

In the same sense, Junges [75] affirms that the meaning of dignity does not admit privileges. It is not a bestowed attribute, but inherent to the person. It is axiological quality that does not admit of gradation. That is, *one can not have more or less dignity, just as one can not be more or less a person* [76],summarizes the author.

This is the notion of dignity that must be interpreted as a constitutional principle to be applied in scientific experiments with humans. For Andorno, what is at stake in the dilemmas of bioethics is the very essence of the human being as a person, who resists its "turning-into-a-thing" [77]. He further argues that *the central concern of bioethics is that biomedical practices be in harmony with respect for human dignity. This is a decisive point of reference for understanding biomedical activity in general and giving it its ultimate goal* [78].

The effect of this conception arises immediately when it refers to scientific research, since dignity manifests itself singularly in the self-determination of the subjects involved. For this reason the concern of the constituent in defining the exceptions imposed on scientific freedom. Scientific activity integrates the first roll of "fundamental rights and guarantees", according to item IX of article 5 of the Brazilian Constitution [65], in this area occurring the most basic violations of rights and fundamental guarantees.

Thus, in promoting and encouraging scientific development, the legislator tried to define two kinds of research, according to article 218: basic scientific research and technological research. In its original wording, the Brazilian Constitution establishes that: paragraph 1: Scientific research will receive priority treatment of the State, in view of the public good and the progress of the sciences. Paragraph 2º: Technological research will focus mainly on solving Brazilian problems and on the development of the national and regional productive system [65].

However, although the Constitution has established scientific freedom as a fundamental right, i does not mean this freedom is absolute. As Fabriz points out, if it is true that *scientific freedom should not be censored, [that] does not mean that its action can go as far as transgressing the principles of the right to life and the dignity of the human person* [79]. This because, the author argues, *what is being debated is how far science can go* *without affecting rights, in which we can glimpse the protection that share the preservation of one's own life* [79]. The limits of scientific freedom must be expressed in possible offenses against other principles derived from human dignity, such as respect for privacy, confidentiality, truthfulness, freedom, the duty to information and consent.

It should be emphasized, therefore, that biomedical interventions in human corporality will be conducted through minute protocols and under the permanent surveillance of the researcher, in order to safeguard the rights of the people involved [80]. For this reason, the right to information and possibilities of intervention in the human body are present, explicitly and implicitly, throughout the constitutional text, and are also introduced in infra-constitutional legislations. In addition to the prerogatives of articles 5 to 17 of the Constitution, in other parts of the document is also implied the principle of human dignity [81].

Among the list of fundamental rights (article 5), the following stand out: equality of all before the law, inviolability of the right to life, freedom and equality (*caput*); equality of rights and obligations between men and women (item I); exclusivity of the law for the creation of obligations for individuals (item II); protection against torture (item III); freedom of thought (item IV); freedom of conscience and belief (clause VI); inviolability of privacy and privacy (item X); access to information (item XIV); right to receive information from public agencies (item XXXIII); guarantee of respect for the physical and moral integrity of prisoners (item XLIX); grant of habeas data to ensure the right to information relating to the person (item LXXII, letter a); among other guarantees of collective rights distributed between Articles 5 and 17 [65].

It should be noted that, based on the precepts of items II and III, the powerful pharmaceutical industry, for example, may question the requirement to submit research on new medicines to CONEP, because it is governed by resolutions. Thus, ethical guidelines regulated by administrative resolutions have proved insufficient to curb abuses.

The principle of human dignity is announced in article 34, item VII, letter b (rights of the human person); Article 225, paragraph 1, item II (requirement of consent of the parents in any case of use of embryonic stem cells for research and therapy, regulated by the Biosafety Law [82]); article 226, paragraph 7 (reproductive rights, guarantee of free decision of the couple on family planning). The latter, regulated by Law 9.263/1996 [83], defines that any intervention in the woman's body should only be performed with due information and consent.

Respect for the dignity announced in the roll of Article 5 of the Brazilian Constitution [65] and in other provisions, as well as infra-constitutional legislation, must be interpreted and applied in accordance with international declarations of rights. In the scope of biomedical studies with individuals, the researcher must observe the guidelines of several international human rights instruments, since they are in the same hierarchical level of constitutional norms [84].

From the provisions of the *International Covenant on Civil and Political Rights* of 1966, Articles 1 (1. All peoples have the right to self-determination), 6 (1. The right to life is inherent in the human person. This right must be protected by the law. Nobody shall be arbitrarily deprived of his/her life), 7º (It shall be forbidden ... to submit a person, without his or her free consent, to medical or scientific experiments), 10 (1. Every person deprived of his liberty shall be treated with humanity and respect for the inherent dignity of the human person) and 17 (1. No one may be the target of arbitrary or illegal interference in his private life, in his family) [53].

From the *American Convention on Human Rights*, Article 5 emphasizes the Right to Personal Integrity (1. Every person has the right to have physical, mental and moral integrity respected. 2. No one shall be subjected to torture, cruel, inhuman or degrading treatment. All persons deprived of their liberty must be treated with respect due to the inherent dignity of the human person). Also article 7, Right to Personal Freedom (1. Everyone has the right to personal liberty and security); and 11, Protection of Honor and Dignity (1. Everyone has the right to respect for his honor and recognition of his dignity) [54].

Although the UDBRH [60] has no binding force in the legal system, because Brazil is a member of UNESCO, its principles must be applied with the Constitutional Law, moreover for the ratification of the instrument by the 191 UN member-states. It should be noted that the UDBRH refers to human dignity and human rights, as provided for in its Article 3, in accordance with the Constitution in its article 1, item III 65. In turn, the conduct of research should be guided by the matrices of articles 4 (benefit and harm), 5(autonomy and individual responsibility), 6 (consent), 7 (disrespect for the ability to consent) and 8 (respect for human vulnerability and individual integrity) [65].

In this way, it is indisputably evident that *dignity is a spiritual and moral value inherent in the person, which manifests itself in the conscious and responsible self-determination of one's own* *life and which brings with it the intent to the requirement of other people, it is the invulnerable minimum that every legal status must ensure, so that only fundamentally, limitations can be made of fundamental rights, but always without neglecting the necessary esteem that all persons deserve as human beings*[85].

Thus, the principle of autonomy is justified as a democratic principle, in which the will and the free consent of the individual are preponderant factors, since these elements are directly linked to the principle of human dignity[19]. Therefore, the dignity of the person supports the principle of protection of participants in scientific studies, accepted by the Constitution, by the Civil Code, by related legislation, deontological standards and jurisprudence of the Brazilian courts[37].

Final considerations

Striving to contribute to the discussion on a new paradigm for conducting clinical research with citizens, one should not lose sight of the characteristics of bioethics in the debate. Indeed, this neologism was already born with a body of open knowledge, as part of the interface of the progress of biology and human and social sciences. Not without reason, it has consolidated itself as a multi, inter and transdisciplinary field for being enriched with the dialogue of the other areas of knowledge. Moreover, by its prima facie validity of the principles of the Anglo-Saxon model of bioethics, its application admits exceptions due to obligations of higher value, being more useful, fairer, and more adequate to protect the dignity of volunteer participants in research, the dignity the researcher and the interests of society.

It is not a matter of defending the normalization of bioethics by rules of law, much less reducing it to ethical-philosophical reflection in its various domains. Moreover, in the creation of new normative guidelines, it is necessary to consider the guarantees that have already been obtained, such as attempts to relax the rules of the *Declaration of Helsinki*[50,86,87]. The concern is to formulate mechanisms to ensure a better balance between individual and collective interests and to avoid violations of the rules, since what is at stake is the protection of legally protected assets such as life, health and physical and mental integrity. It is at this point that the need for a connection between a national bioethics and human rights is considered, since, although they belong to different spheres of practical knowledge, they have the same object in common - human action.

Although it is recognized that principlism can account for most of the conflicts and dilemmas experienced in clinical practice and research, it is insufficient when applied to public health and research in the so-called dependent countries, since their conditions are substantially different from those of the nation in which it was thought the main proposal[4]. However, the criticism of this model does not represent a peaceful consensus, since this framework still exerts a lot of influence on Brazilian researchers in the area of health[3], because of its practicality or its guidelines in clinical procedures. However, this does not invalidate the discussion on the regulatory improvement in this sector before a framework governed by administrative resolution, in which the resources of the sanctions will only be possible by legal rule.

It is known that in recent years Brazil has become one of the most prolific emerging countries in research, where there is a significant growth of studies aimed at hospitalized patients, which become part of routine care[88]. The country also presents significant outsourcing of clinical trials, but, on the other hand, about *80% of studies related to the development of new drugs are conducted by multinational companies*[89].

In summary, this paper tried to demonstrate the insufficiency of the North American current as regulatory framework of administrative norms for the social control of the researches with human beings, as well as the pertinence of the principle of the human dignity as a new paradigm established by law, under the prism of constitutional bioethics.

Referências

1. Potter VR. Bioethics: bridge to the future. New Jersey: Prentice-Hall; 1971.
2. Reich WT. The word "bioethics": its birth and the legacies of those who shaped it. Kennedy Inst Ethics J [Internet]. 1994 [acesso 7 ago 2018];4(4):319-35. Disponível: https://bit.ly/2M9oFSZ
3. Figueiredo AM, França GV. Bioética: uma crítica ao principialismo. Derecho y Cambio Social [Internet]. 2009 [acesso 20 out 2016];6(17):1-20. Disponível: https://bit.ly/2rvpyZL
4. Schramm FR, Palácios M, Rego S. O modelo bioético principialista para a análise da moralidade da pesquisa científica envolvendo seres humanos ainda é satisfatório? Ciênc Saúde Coletiva [Internet]. 2008 [acesso 7 ago 2018];13(2):361-70. Disponível: https://bit.ly/2ORmcuT

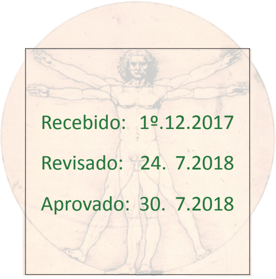
5. Durand G. Introdução geral à bioética: história, conceitos e instrumentos. São Paulo: Loyola; 2003.
6. Beecher HK. Ethics and clinical research. N Engl J Med [Internet]. 1966 [acesso 7 ago 2018];274(24):1354-60. Disponível: https://bit.ly/2Okq6LI
7. Vieira S, Hossne WS. Experimentação com seres humanos. São Paulo: Moderna; 1987.
8. Gracia D. Procedimientos de decisión en ética clínica. Madrid: Triacastela; 2007. p. 31.
9. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont report: ethical principles and guidelines for the protection of human subjects of research. In: Post SG, editor. Encyclopedia of bioethics. 3ª ed. New York: Macmillan; 2003. p. 2822-4.
10. Jonsen AR. The birth of bioethics. New York: Oxford University Press; 2003.
11. Beauchamp TL, Childress JF. Principles of biomedical ethics. New York: Oxford University Press; 1979.
12. Beauchamp TL, Childress JF. Princípios de ética biomédica. São Paulo: Loyola; 2002.
13. Figueiredo AM. O ensino da bioética na pós-graduação stricto sensu da área de ciência da saúde no Brasil [tese] [Internet]. Brasília: Universidade de Brasília; 2009 [acesso 7 ago 2018]. p. 17. Disponível: https://bit.ly/2Ol7Ule
14. Mori M. A bioética: sua natureza e história. Humanidades [Internet]. 1994 [acesso 7 ago 2018];9(4):332-41. Disponível: https://bit.ly/2LYjO7M
15. Oliveira AAS. Bioética e direitos humanos. São Paulo: Loyola; 2011.
16. Organização das Nações Unidas. Declaração universal dos direitos humanos [Internet]. Rio de Janeiro: Onu; 2009 [acesso 7 ago 2018]. Disponível: https://uni.cf/2sXdl3e
17. Oliveira MLC. Comitê de ética em pesquisa no Brasil: um estudo das representações sociais. Brasília: Universa; 2004.
18. Anjos MF. Bioética: abrangência e dinamismo. In: Barchifontaine CP, Pessini L, organizadores. Bioética: alguns desafios. São Paulo: Loyola; 2001. p. 17-34.
19. Fabriz DC. Bioética e direitos fundamentais: a bioconstituição como paradigma do biodireito. Belo Horizonte: Mandamentos; 2003.
20. Garrafa V. Da bioética de princípios a uma bioética interventiva. Bioética [Internet]. 2005 [acesso 7 ago 2018];13(1):125-34. Disponível: https://bit.ly/2fRTUPF
21. Conselho Nacional de Saúde. Resolução CNS nº 196, de 10 de outubro de 1996. Aprova diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos [Internet]. Diário Oficial da União. Brasília, nº 201, 16 out 1996 [acesso 28 abr 2018]. Disponível: https://bit.ly/1de8q1m
22. Brasil. Câmara dos Deputados. Projeto de Lei nº 7.082, de 13 de março de 2017. Origem: Projeto de Lei do Senado nº 200, de 2015. Dispõe sobre a pesquisa clínica com seres humanos e institui o Sistema Nacional de Ética em Pesquisa Clínica com Seres humanos [Internet]. Brasília: Senado Federal; 2017 [acesso 28 abr 2018]. Disponível: https://bit.ly/2KMNMaz
23. Clouser KD, Gert B. A critique of principlism. J Med Philos [Internet]. 1990 [acesso 7 ago 2018];15(2):219-36. Disponível: https://bit.ly/2jUDitx
24. Holm S. Not just autonomy: the principles of American biomedical ethics. J Med Ethics [Internet]. 1995 [acesso 7 ago 2018];21(6):332-8. Disponível: https://bit.ly/2vrjt3l
25. Gert B, Culver CM, Clouser KD. Principlism. In: Gert B. Bioethics: a return to fundamentals. New York: Oxford University Press; 1997. p. 71-92.
26. Gert B, Culver CM, Clouser KD. Principlism. In: Gert B, Culver CM, Clouser KD. Bioethics: a systematic approach. 2ª ed. New York: Oxford University Press; 2006.
27. Engelhardt Jr HT. The foundations of bioethics. 2ª ed. New York: Oxford University Press; 1996.
28. Campbell AV. Uma visão internacional da bioética. In: Garrafa V, Costa SIF, organizadores. A bioética no século XXI. Brasília: Editora UnB; 2000. p. 25-35.
29. Neves MCP. A fundamentação antropológica da bioética. Bioética [Internet]. 1996 [acesso 4 mar 2018];4(1):7-16. p. 13. Disponível: https://bit.ly/2AjTttw.
30. Tealdi JC. Los princípios de Georgetown: análisis crítico. In: Garrafa V, Kottow M, Saada A, coordenadores. Estatuto epistemológico de la bioética. Ciudad de México: Unesco; 2005. p. 36-54.
31. Kottow M. Bioética prescriptiva: la falacia naturalista: el concepto de principios en bioética. In: Garrafa V, Kottow M, Saada A, coordenadores. Op. cit. p. 25-44.
32. Azambuja LEO, Garrafa V. A teoria da moralidade comum na obra de Beauchamp e Childress. Rev. bioét. (Impr.) [Internet]. 2015 [acesso 7 ago 2018];23(3):634-44. Disponível: https://bit.ly/2MqXCPI
33. Garrafa V, Martorell LB, Nascimento WF. Críticas ao principialismo em bioética: perspectivas desde o norte e desde o sul. Saúde Soc [Internet]. 2016 [acesso 2 fev 2018]; 25(2):442-51. Disponível: https://bit.ly/2PLSmb6.
34. Clouser KD, Gert B. Op. cit. p. 221.
35. Engelhardt Jr HT. Fundamentos da bioética. São Paulo: Loyola; 1998. p. 17.
36. Schmidt AV, Tittanegro GR. A autonomia principialista comparada a autonomia do libertarismo. Rev Pistis Prax Teol Pastor [Internet]. 2009 [acesso 20 set 2017];1(1):173-98. Disponível: https://bit.ly/2K2tNnb
37. Guz G. O consentimento livre e esclarecido na jurisprudência dos tribunais brasileiros. Rev Direito Sanit [Internet]. 2010 [acesso 7 ago 2018];11(1):95-122. p. 100. Disponível: https://bit.ly/2KCdLjX
38. Katz J. The silent world of doctor and patient. New York: Free Press; 1984. p. 48.
39. Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press; 1986.

40. Neves MCP, coordenadora. Comissões de ética: das bases teóricas à actividade quotidiana. 2ª ed. Coimbra: Gráfica Coimbra; 2002. p. 179.
41. Alves JV. Ensaios clínicos. Coimbra: Coimbra Editora; 2003. p. 297. (Série Direito Biomédico, nº 8).
42. Garrafa V, Kottow M, Saada A. Bases conceituais da bioética: enfoque latino-americano. São Paulo: Gaia; 2006. p. 51.
43. Kottow M. Op. cit. p. 38.
44. Azambuja LEO, Garrafa V. Op. cit. p. 638.
45. Garrafa V, Kottow M, Saada A. Op. cit.
46. Andorno R. Global bioethics at Unesco: in defense of the Universal Declaration on Bioethics and Human Rights. J Med Ethics [Internet]. 2007 [acesso 7 ago 2018];33(3):150-4. Disponível: https://bit.ly/2OQu3ZC
47. Oliveira AAS. Interface entre bioética e direitos humanos: o conceito ontológico de dignidade humana e seus desdobramentos. Rev. Bioética [Internet]. 2007 [acesso 7 ago 2018];15(2):170-85. Disponível: https://bit.ly/2MaVgrr
48. Campbell AV. Op. cit. p. 34.
49. Trials of war criminals before the Nüremberg Military Tribunals. Washington: US Government Printing Office; 1949.
50. Associação Médica Mundial. Declaração de Helsinque da Associação Médica Mundial (WMA) [Internet]. Fortaleza: WMA; 2013 [acesso 27 abr 2018]. Disponível: https://bit.ly/2MP2H4A
51. Andorno R. Bioética y dignidad de la persona. 2ª ed. Madrid: Tecnos; 2012.
52. Pessini L. Algumas notas sobre uma bioética de cunho asiático, a partir da China. Bioethikos [Internet]. 2014 [acesso 7 ago 2018];8(2):161-73. Disponível: https://bit.ly/2M9eOwy
53. Brasil. Decreto nº 592, de 6 de julho de 1992. Atos internacionais. Pacto internacional sobre direitos civis e políticos. Promulgação [Internet]. Diário Oficial da União. Brasília, 7 jul 1992 [acesso 27 abr 2018]. Disponível: https://bit.ly/1hlaXRZ
54. Brasil. Decreto nº 678, de 6 de novembro de 1992. Promulga a Convenção americana sobre direitos humanos (Pacto de São José da Costa Rica), de 22 de novembro de 1969 [Internet]. Diário Oficial da União. Brasília, p. 15562, 9 nov 1992 [acesso 27 abr 2018]. Seção 1. Disponível: https://bit.ly/2D5CuhN
55. Conselho de Organizações Internacionais de Ciências Médicas. Diretrizes éticas internacionais para a pesquisa biomédica em seres humanos. São Paulo: Loyola; 2004.
56. Council for International Organizations of Medical Sciences. International ethical guidelines for health-related research involving humans [Internet]. Geneva: Cioms; 2016 [acesso 11 maio 2018]. Disponível: https://bit.ly/2rzX9BO
57. Council of Europe. Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: convention on human rights and biomedicine [Internet]. Oviedo: Council of Europe; 1997 [acesso 28 abr 2018]. (European Treaty Series, nº 164). Disponível: https://bit.ly/29P24qi
58. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração universal sobre o genoma humano e os direitos humanos [Internet]. Brasília: Unesco; 1997 [acesso 27 abr 2018]. Disponível: https://bit.ly/2oNe3x4
59. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração internacional sobre os dados genéticos humanos [Internet]. Paris: Unesco; 2003 [acesso 28 abr 2018]. Disponível: https://bit.ly/2oDqgUt
60. Organização das Nações Unidas para a Educação, a Ciência e a Cultura. Declaração universal sobre bioética e direitos humanos [Internet]. Paris: Unesco; 2005 [acesso 28 abr 2018]. Disponível: https://bit.ly/1TRJFa9
61. Equipe editorial. Apresentação: carta de Buenos Aires sobre bioética y derechos humanos. Rev Bras Bioética [Internet]. 2005 [acesso 7 ago 2018];1(3):317-22. Disponível: https://bit.ly/2KBUkYc
62. Gros Espiell H. La declaración universal sobre bioética y derechos humanos de la Unesco y la declaración de Santo Domingo sobre bioética y derechos humanos. Rev Bras Bioética [Internet]. 2007 [acesso 7 ago 2018];3(1):7-13. Disponível: https://bit.ly/2Olz8rY
63. Escobar AL. A bioética na América Latina e na Colômbia. In: Pessini L, Barchifontaine C, organizadores. Bioética na Ibero-América: histórias e perspectivas. São Paulo: Loyola; 2007. p. 63-76.
64. Porto D. Bioética de intervenção: retrospectiva de uma utopia. In: Porto D, Garrafa V, Martins ZG, Barbosa SN, organizadores. Bioéticas, poderes e injustiças: 10 anos depois [Internet]. Brasília: CFM; 2012 [acesso 9 nov 2018]. p. 109-26. Disponível: https://bit.ly/2FcG3nn
65. Brasil. Constituição da República Federativa do Brasil de 1988 [Internet]. Diário Oficial da União. Brasília, 5 out 1988 [acesso 28 abr 2018]. Disponível: https://bit.ly/1bIJ9XW
66. Sarlet IW. Dignidade da pessoa humana e direitos fundamentais na Constituição Federal de 1988 [Internet]. 8ª ed. Porto Alegre: Livraria do Advogado; 2010 [acesso 28 abr 2018]. Disponível: https://bit.ly/2JUQESU
67. Conselho Nacional de Saúde. Resolução nº 1, de 1988. Aprova as normas de pesquisa em saúde [Internet]. Brasília: Conselho Nacional de Saúde; 1988 [acesso 22 set 2016]. Disponível: https://bit.ly/2ruwdE9
68. Duarte LFD. A ética em pesquisa nas ciências humanas e o imperialismo bioético no Brasil. Rev Bras Sociol [Internet]. 2015 [acesso 22 set 2016];3(5):29-52. p. 32. Disponível: https://bit.ly/2AVFryD

69. Conselho Nacional de Saúde. Resolução CNS nº 466, de 12 de dezembro de 2012. Aprova diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos [Internet]. Diário Oficial da União. Brasília, nº 12, p. 59, 13 jun 2013 [acesso 11 maio 2018]. Disponível: https://bit.ly/2KeJPu8
70. Conselho Nacional de Saúde. Resolução CNS nº 510, de 7 de abril de 2016. Dispõe sobre as normas aplicáveis a pesquisas em ciências humanas e sociais [Internet]. Brasília: CNS; 2016 [acesso 28 jul 2018]. Disponível: https://bit.ly/2OqTAIS
71. Séguin E. Biodireito. 4ª ed. Rio de Janeiro: Lumen Juris; 2005. p. 50.
72. Fabriz DC. Op. cit. p. 19.
73. Conselho Nacional de Saúde. Carta aberta à sociedade: Projeto de Lei nº 200/2015: um desserviço à sociedade brasileira [Internet]. Brasília: CEP/Conep; 14 maio 2015 [acesso 10 maio 2018]. Disponível: https://bit.ly/2IvS8Vi
74. Oliveira AAS. Op. cit. 2011. p. 91.
75. Junges JR. Bioética: hermenêutica e casuística. São Paulo: Loyola; 2006.
76. Junges JR. Op. cit. p. 133.
77. Andorno R. Op. cit. 2012. p. 68.
78. Andorno R. Op. cit. 2012. p. 35.
79. Fabriz DC. Op. cit. p. 287.
80. Duarte LFD. Op. cit. 2015. p. 36-7.
81. Sarlet IW, Marinoni LG, Mitidiero D. Curso de direito constitucional. 6ª ed. Rio de Janeiro: Saraiva; 2017.
82. Brasil. Lei nº 11.105, de 24 de março de 2005. Regulamenta os incisos II, IV e V do § 1º do art. 225 da Constituição Federal e dá outras providências [Internet]. Diário Oficial da União. Brasília, 28 mar 2005 [acesso 27 abr 2018]. Disponível: https://bit.ly/2K0S9O0
83. Brasil. Presidência da República. Lei nº 9.263, de 12 de janeiro de 1996. Regula o § 7º do art. 226 da Constituição Federal, que trata do planejamento familiar, estabelece penalidades e dá outras providências [Internet]. Diário Oficial da União. Brasília, 15 jan 1996 [acesso 27 abr 2018]. Disponível: https://bit.ly/2FTDPEB
84. Paulo V, Alexandrino M. Direito constitucional descomplicado. 16ª ed. São Paulo: Método; 2017.
85. Moraes A. Direito constitucional. 29ª ed. São Paulo: Atlas; 2007. p. 16.
86. Garrafa V, Prado MM. Alterações na Declaração de Helsinque: a história continua. Rev. Bioética [Internet]. 2007 [acesso 2 ago 2018];15(1):11-25. Disponível: https://bit.ly/2nm5nLS
87. Figueiredo AM. Diretrizes éticas internacionais em pesquisa: crítica à Declaração de Helsinque. Derecho Cambio Social [Internet]. 2011 [acesso 11 maio 2018];8(24):1-15. Disponível: https://bit.ly/2NvEmVX
88. Zucchetti C, Morrone FB. Perfil da pesquisa clínica no Brasil. Rev HCPA [Internet]. 2012 [acesso 8 ago 2018];32(3):340-7. Disponível: https://bit.ly/2OU7pj6
89. Zucchetti C, Morrone FB. Op. cit. p. 343.

Correspondência
Rua Antônio Parreira, 15, apt. 1.301, Boa Viagem CEP 24210-320. Niterói/RJ, Brasil.

Antônio Macena Figueiredo – Doutor – macenaso@yahoo.com.br



Recebido: 1º.12.2017
Revisado: 24. 7.2018
Aprovado: 30. 7.2018