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Conditions for involving persons who are not able to consent in biomedical research under article 17 of the Oviedo Convention. Too permissive or too prohibitive?

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Abstract

The Oviedo Convention, one of the most significant documents concerning bioethics, represents the first legally binding text on international biomedical law and ethics.[1] However, in literature, it has been characterised as a poor document, unable to face most bioethical issues[2] and to adequately illustrate the human rights philosophical pattern in favour of which it has been issued.[3] One of the Convention's most controversial articles,[4] Article 17 regarding the protection of persons unable to consent to research, was met with great opposition and it was finally accepted with suspicion.[5] The permissive character of the article was a major reason for the opposition.[6] This work intends to explain why Article 17 is too permissive. It is argued that the conditions for involving incapacitated persons in biomedical research, specified by Article 17, are only seemingly prohibitive. In a closer examination and compared to equivalent articles of International Treaties, these conditions can mostly be characterised as too permissive and consequently, less protective. This is justified by considering the Article's inadequacy to address ethical challenges in respect to key notions such as the consent capacity, surrogate decision-making, risk-benefits balance, advance

[1] ***S. E. Salako,*** "Informed consent under the European Convention on Biomedicine and the UNESCO Declaration on Bioethics", *Medicine and law*, 2011, Vol. 30 (1), pp. 104.
[2] ***M. Moril / D. Neri,*** "Perils and Deficiencies of the European Convention on Human Rights and Biomedicine", *Journal of Medicine and Philosophy*, 2001, Vol. 26 (3), pp. 324.
[3] ***G. Hottois,*** "A Philosophical and Critical Analysis of the European Convention of Bioethics", *Journal of Medicine and Philosophy*, 2000, Vol. 25 (2), pp. 133.
[4] ***M. A. M. De Wachter,*** "The European Convention on Bioethics", *The Hastings Center Report*, 1997, Vol. 27 (1), pp. 15.
[5] ***G. Hottois,*** *op. cit.*
[6] ***A. Hendriks***, "Article 17 of the European Convention on Human Rights and Biomedicine: incompatible with international human rights law?", *Kritische Vierteljahresschrift für Gesetzgebung und Rechtswissenschaft (KritV)*, 1998, Vol. 81 (1), pp. 114.

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directives, participation in research in emergency circumstances and the research participants' assent. It is argued that the article's approach is too simplistic and free to interpretation. As such it unsafely facilitates the participation of incapacitated individuals in biomedical research, while the individuals' opportunity for participation remains depended on their representatives and the interpretation of Article 17 instead of reflecting the principle of respect for autonomy. Also,the omission ofadditional conditions that could enhance maximally autonomous decisions, limits the value of informed consent in favour of the facilitation of the process concerning the selection of participants. Consequently, it becomes evident that Article 17 incorporates features that confirm its permissive character.

Keywords: Oviedo Convention, Article 17, conditions, biomedical research, consent capacity, autonomy.

Όροι για τη συμμετοχή ατόμων, ανίκανων να δώσουν συγκατάθεση, σε βιοιατρική έρευνα σύμφωνα με το άρθρο 17 της Σύμβασης του Οβιέδο. Είναι οι όροι αυτοί υπερβολικά ενδοτικοί ή απαγορευτικοί;

Περίληψη

Η Σύμβαση του Οβιέδο, ένα από τα σημαντικότερα έγγραφα σχετικά με τη βιοηθική, αποτελεί το πρώτο δεσμευτικό κείμενο διεθνούς βιοϊατρικού δικαίου και ηθικής. Ωστόσο, στη βιβλιογραφία, έχει χαρακτηριστεί ως ένα φτωχό έγγραφο, ανίκανο να αντιμετωπίσει τα περισσότερα βιοηθικά ζητήματα και να απεικονίσει επαρκώς το φιλοσοφικό πρότυπο των ανθρώπινων δικαιωμάτων υπέρ του οποίου συντάχθηκε. Ένα από τα πιο αμφιλεγόμενα άρθρα της Σύμβασης, το Άρθρο 17 συνάντησε έντονη αντίσταση και τελικά έγινε αποδεκτό με καχυποψία. Ο ενδοτικός χαρακτήρας του Άρθρου, το οποίο αφορά στην προστασία ατόμων που δεν μπορούν να συναινέσουν σε έρευνα, ήταν ένας σημαντικός λόγος αυτής της αντίστασης. Η παρούσα εργασία σκοπεύει να εξηγήσει γιατί το Άρθρο 17 είναι υπερβολικά ενδοτικό. Υποστηρίζεται ότι οι όροι για τη συμμετοχή στη βιοϊατρική έρευνα ατόμων με ανικανότητα συναίνεσης, όπως αυτοί καθορίζονται στο Άρθρο 17, είναι φαινομενικά μόνο απαγορευτικοί. Με μια πιο προσεκτική εξέταση και συγκριτικά με αντίστοιχα άρθρα Διεθνών Συνθηκών, οι όροι αυτοί μπορούν να χαρακτηριστούν ιδιαίτερα ενδοτικοί και συνεπώς λιγότερο προστατευτικοί. Αυτό επιβεβαιώνεται λαμβάνοντας υπόψη την ανεπάρκεια του Άρθρου να απαντήσει σε ηθικές προκλήσεις που αφορούν βασικές

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έννοιες όπως την ικανότητα συγκατάθεσης, τη λήψη αποφάσεων μέσω εκπροσώπων, την ισορροπία κινδύνου-οφέλους, τις διαθήκες ζωής, τη συμμετοχή σε έρευνα σε περιπτώσεις έκτακτης ανάγκης και την σύμφωνη γνώμη των συμμετεχόντων στην έρευνα. Σε αυτή την εργασία υποστηρίζεται ότι η προσέγγιση του Άρθρου είναι απλουστευτική και ελεύθερη ερμηνείας. Συνεπώς, διευκολύνει επισφαλώς τη συμμετοχή στη βιοϊατρική έρευνα ατόμων μη ικανών να συναινέσουν, ενώ η δυνατότητα συμμετοχής τους, αντί να αντικατοπτρίζει την αρχή σεβασμού της αυτονομίας, εξαρτάται από τους εκπροσώπους αυτών των ατόμων και την ερμηνεία του Άρθρου 17. Επιπλέον, η παράλειψη πρόσθετων όρων ικανών να ενισχύσουν αυτόνομες αποφάσεις, περιορίζει την αξία της ενημερωμένης συναίνεσης υπέρ της διευκόλυνσης της διαδικασίας επιλογής συμμετεχόντων. Συνεπώς, γίνεται φανερό ότι το Άρθρο 17 ενσωματώνει χαρακτηριστικά που επιβεβαιώνουν τον ανεκτικό χαρακτήρα του.

1. Introduction

The 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 (ECHRB) is one of the most significant documents, in respect to bioethics, as itrepresents the first legally binding text on international biomedical law and ethics.[7]In literature, it has been argued that the Convention is a poor document, unable to face most bioethical issues[8] and it does not adequately illustrate the human rights philosophical pattern in favour of which it has been issued.[9]

Criticism was raised since the Draft Bioethics Convention was presented few years before it was eventually signed in 1997. One of the most controversial topics was the one concerning research with incapacitated persons, which constituted a major issue especially in the German debate.[10] Article 17 of the Convention regarding the protection of persons not able to consent to research was met with great opposition and after extensive discussions and amendments, it was accepted with suspicion in the final form of the Convention that was signed by the European member states. The permissive character of

[7] ***S. E. Salako***, *op. cit*.
[8] ***M. Moril /D. Neri***,*op. cit*.
[9] ***G. Hottois***, *op. cit*.
[10] ***M. A. M. De Wachter***, *op. cit.*

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the Article was a major reason for the opposition[11] and the Explanatory Report that followed the Convention validates to an extent the preliminary suspicion.[12]

The present paper explains if such criticism was justifiable by exploring whether the conditions for involving persons who are not able to consent in biomedical research specified by the Article 17 of the Convention are too permissive or too prohibitive. Key notions which constitute ethical challenges in respect to the research involving persons unable to consent, such as the notion of consent capacity, surrogate decision-making, the balance between risks and benefits, advance directives, participation in research in emergency circumstances and the assent of research participants can either limit or facilitate the participation in research depending on the way these are perceived and whether they are taken into consideration. In order to come up with a justifiable conclusion, the paper explores how adequately, if at all, Article 17 illustrates these key notions in comparison to the literature's approach and equivalent articles of International Treaties addressing ethical issues in clinical research involving incapacitated individuals. It will be argued that while aspects of Article 17 seem to be prohibitive, overall, it is mostly permissive. Nevertheless, primarily it is necessary to point out the aspects of Article 17 of the ECHRB which are under scrutiny in this paper.

2. Article 17 of the ECHRB

'Making informed decisions about research participation is often a difficult issue for the general public, given the complexities of research protocols'.[13]Incapacity of persons to consent in research can further complicate the decision-making process. Albeit, it would be discriminative not to consider provisions to enable their participation in biomedical research. Prohibition of incapacitated individuals to become research participants would deprive themfrom potential direct health benefits or would deprive others with similar condition to obtain health benefit.

[11]***A. Hendriks***, *op. cit.*
[12]***G. Hottois***, *op.cit.*
[13]**R. *I. Freedman***, "Ethical Challenges in the Conduct of Research Involving Persons with Mental Retardation", *Mental Retardation*, 2001, Vol. 39 (2), pp. 130.

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International human rights instruments, as the ECHRB, aim amongst others to provide a protective net for the participation of individuals in medical research.[14] Towards this direction, Article 17 of the ECHRB sets the conditions according to which persons unable to consent to research are eligible to participate in biomedical research.

Briefly, the aspects of the Article which constitute the main focus of this paper require that, under such circumstances, participation to the research can be allowedif the results of the research have the potential to produce real and direct benefit to the participant's health, research of comparable effectiveness cannot be carried out on individuals capable of giving consent, the necessary authorization under article 6 has been given specifically and in writing and, the individual does not object.[15] The conditions stated in the Articles 16 and 6 are taken into consideration in the first paragraph of Article 17 and they respectively refer to the protection of persons undergoing research[16] and the protection of persons not able to consent.[17] The points of article 6 which will be examined below are the one requiring that 'an intervention may be carried out for his direct benefit', the one stating that 'where an adult does not have the capacity to consent because of mental disability, disease or similar reason…the research subject shall as possible take part in the authorization procedure' and the one stating that 'authorization may be withdrawn at any time in the best interest of the person concerned'.[18]

In the second paragraph of Article 17, which also takes under consideration the points of the first paragraph as mentioned above, it is stated that, 'exceptionally, if the research has no direct benefit to the health of the individual concerned, such research may be authorized when research has the aim of contributing... in the scientific understanding of the individuals disease or to other individuals in the same age category or afflicted with the same disease, only if the research entails minimal risks and minimal burden for the individual concerned'.[19]

[14]**H. *D. C. R. Abbing***, "The convention on human rights and biomedicine: An appraisal of the council of Europe convention", *European Journal of Health Law*, 1998, Vol. 5, pp. 377.

[15]***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", *Journal of Medicine and Philosophy*, 2000 Vol. 25 (2), pp. 262–263.

[16]*Ibid*.pp. 262.

[17]*Ibid*.pp. 260.

[18]*Ibid.*

[19]*Ibid*.pp.263.

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At first sight, particularly the first paragraph, can be characterised as prohibitive enough, especially if one considers the inevitable existence of necessary protective constraints. However, after detailed examination of the Article it becomes evident that it is too permissive. Certain points of deficiency can also justify this approach.Considering the language used in Article 17, the repetition of emphatic phrases, such as "only if all the following conditions are met […]the results of the research have the potential to produce real and direct benefit real […] the research entails only minimal risk and minimal burden for the individual concerned",[20]add a restrictive character to the article. However, it appears that there are points where the language misses the substance. And this becomes obvious by comparing primarily the Article 17 standards to international standards and recommendations for the inclusion of incapacitated persons in biomedical research.

3. The Article 17 standards compared to international standards and recommendations for the inclusion of incapacitated persons in biomedical research

3.1 The Code of Nuremberg and the CCPR

The permissive character of Article 17 is evident if one compares it with the Code of Nuremberg and the CCPR approach to the issue of incapacitated people participation in research. As a response to the Second World War's atrocities, the Code was adopted in 1947 and it was prohibiting the involvement of incapacitated persons in non-therapeutic medical.[21,22]Similarly, 'Article 7 of the International Covenant on Civil and Political Rights (CCPR) prohibits involvement of research subjects in medical and scientific experimentation without their consent'.[23]The CCPR's different and more strict approach to the issue is also well observed in the "General Comment" about the meaning of Article 7 composed by 'the Human Rights Committee, a body established under the CCPR and in charge of the supervision and control of the implementation by State Parties of their treaty obligations'[24] According to the Committee's comment:"3. The text of article 7 allows no limitation […] 7. Article 7 expressly prohibits medical or scientific experimentation without the free consent

[20]*Ibid*. pp. 262-263.
[21]***N. Code***, "The Nuremberg Code", *Trials of war criminals before the Nuremberg military tribunals under control council law*, 1949, Vol. 10, pp. 181-182.
[22]***A. Hendriks***, *op. cit*., pp. 113.
[23]*Ibid*.
[24]*Ibid*. pp. 114.

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of the person concerned. […] 21. The Committee is concerned that, in some States, non-therapeutic research may be conducted on minors or mentally-ill patients on the basis of surrogate consent, in violation of the provisions of article 7".[25]

Compared to the Code and the CCPR, Article 17 of the Oviedo Convention seems to express a more "contemporary" approach to the notion of informed consent and the rights of incapacitated people.[26] Article 17 does not only clearly permit incapacitated individuals to participate in medical research under certain conditions, but also, it does not include any specification about the type of research, either therapeutic or non-therapeutic.This approach can be seen as favourable for incapacitated individuals as it facilitates participation in research and consequently access to potential health benefits. Permissiveness to this extent can be seen as welcomed. However, by rigorously examining the conditions included in Article 17, one can come across with various elements that attribute to the Article an over-permissive character.

3.2 Balance between benefits and risks

An argument justifying the permissive character of Article 17 can be derived by examining the way benefits and risks are balanced or not balanced in this article. Among the conditions in respect to the protection of persons not able to consent to research, it is required the potential to produce real and direct benefit to the participant's health or results capable of conferring benefit to the person concerned or other persons…, while in respect to risks, only minimal risk, and burden for the individual concerned is acceptable.[27]

Nevertheless, the Article does not include specific definition of level of minimal risk or potential therapeutic benefit.Essentially, in Article 17 it has not been considered that what is minimal risk for one person may create greater risk for another person.[28]According to the first paragraph of Article 17, while there is explicit request for direct benefit there is no protective provision against any potential risk. However, even if one accepts that the incapacitated participant's representative can make a sensible decision measuring benefits and risks, the risks for the participant can subjectively be high. In the unlike case that the

[25]*Ibid*. 114-115 ***A. Hendriks*** citing: General Comment No. 20 (1992), replacing General Comment No. 7 (1982), as published in *International Human Rights Reports* 1994 Vol. 1 (2), pp. 26-28.
[26]*Ibid*.pp. 13.
[27]***Council of Europe***, *op. cit*., pp. 262-263.
[28]***R. I. Freedman***, *op. cit*., pp. 136.

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participant cannot consent, it cannot be denied that he is not able to evaluate the risks basing the judgement on his individual perception. Also, regarding the second paragraph of the article, even though there is reference to both benefits and risks, there is no request for the benefits to outweigh the minimal risks. If such a condition existed, then it would be more difficult to justify involvement in research for an incapacitated individual.Further to the observation of ambiguity regarding the meaning of the concepts of minimal risk and therapeutic benefit in the Article, arguably it can be supported that the conditions are flexible to interpretation and this can function either against or in favour of the participant. In either scenario, though, this flexibility allows greater ease to involve incapacitated individuals in biomedical research.

This argument is reinforced if one considers Article 18 of the Ethical Principles for Medical Research Involving Human Subjects in Declaration of Helsinki 2000. In this article, it is stated that 'medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject'.[29] Also, Article 17 of the ECHRB compared to the equivalent Article 18 of the Draft Additional Protocol to the Convention on Human Rights and Biomedicine, on Biomedical Research 2001 in respect to the issue of benefits and risks, occurs less protective and more permissive. This is because Article 18 clearly sets barriers to risks by including the condition that 'any consideration of additional potential benefits of the research shall not be used to justify an increased level of risk or burden'.[30]

Furthermore, the draft 2001 Guidelines of the Council for International Organizations of Medical Sciences (CIOMS), among its guidelines, it states that the risk of participation in such research "should be no more likely and not greater than the risk attached to routine medicalor psychological examination of such patients'[31], an approach which also represents an obvious threshold to the potential risks and consequently, an indisputable constraint to the participation in research for incapacitated individuals.

[29]***World Medical Association,*** 'World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects', *Bulletin of the World HealthOrganization*, 2001, Vol. 79 (4), pp. 374.

[30]***Council of Europe Steering Committee on Bioethics (CDBI),*** *Draft Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research,* Europe, 2001, pp. 9.

[31]***Council for International Organizations of Medical Sciences****, Draft Revision of CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects(1993)*, Tokyo-Inuyama, 2001, guideline 9, pp. 33-34.

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Thus, taking under consideration the above comparisons, even though Article 17 in exceptional cases, as those which are set in the second paragraph, places constraints which can reduce the number of incapacitated participants, as it requires that the beneficiaries should be at the same age category or afflicted with the same disease or disorder as the one of the participant, it becomes evident that the simplistic way that it deals with the terms of benefits and risks upgrades it to more permissive than equivalent official recommendations.

3.3 Surrogate decision-making and advance directives

The same simplistic approach is adopted in respect to the role of surrogates in decision-making. Since the principle of informed consent is the leading principle for medical intervention and research and supports the idea of the inviolability of the human body,[32] it would be unethical to be omitted even in circumstances of intervention or research that the involved subject is unable to consent. Therefore, according to the widely-accepted method of asking a qualified surrogate or proxy to provide consent for research participation on behalf of an individual who is incapable to consent[33], Article 17 does include such a condition, as well as, it requires that the research subject shall as possible take part in the authorization procedure.[34]However, it does not include other requirements found in different guidelines, which can potentially limit the access to research but they can secure a valid informed consent which is the expression of the incapacitated person's autonomy.[35]

In particular, there is no recommendation predicting assistance for the research subject to take part as possible in the decision-making procedure. On one hand, there is research evidence that 'surrogates often do not know, misinterpret, or disregard the perceived preferences of incapacitated individuals',[36] while on the other hand, the capacity to consent is deferent among incapacitated individuals. It cannot exist at all, but it can also be limited. Particularly individuals with mental retardation can be informed and trained to be able to comprehend their rights and responsibilities to make decision about research.[37]In addition,

[32]***A. Hendriks**, op. cit*., pp. 112.
[33]***R. I. Freedman**, op. cit*., pp. 135.
[34]***Council of Europe*** at footnote 15, *op. cit*., pp. 260.
[35]***A. M. Duguet / B. Boyer-Beviere**,* "Consent to medical research of vulnerable subjects from the French point of view: the example of consent in research in the case of Alzheimer disease", *Medicine and Law*, 2011, Vol. 30, pp. 613.
[36]***R. I. Freedman**, op. cit*., pp. 135.
[37]*Ibid*. 138.

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although the authorization may be withdrawn at any time in best interest of the person concerned[38] who can also raise objection about the research, the concept of advanced directives or the option of assent[39] are not taken under consideration among the conditions of the Article 17.

On the contrary, the United Nations Convention on the Rights of Persons with Disabilities (CRPD) 2008[40] does include appropriate provisions related to information and communication so that the incapacitated individuals will be able to take part in decision-making,[41] while the Helsinki Declaration takes under consideration the incompetent subject's assent to decisions when this is possible to be obtained.[42,43]In respect to provisions about advanced directives, there has been debate about their inclusion in research as they are expected to have relevance for advance research consent decisions.[44] Their value has been acknowledged in the Draft Protocol on Biomedical Research 2001. In Article 18 of the document it is clearly stated that previously expressed wishes and objections of the research subject should be taken into account.[45] Furthermore, the Directive (2001/20/EC) of the European parliament not only takes into consideration in its Article 5 previously expressed wishes of persons not able to consent,[46] but it also gives to them direct legal effect.[47] Nevertheless, Article 17 of the ECHRB, does not address advance directives. Although Article 9 of the ECHRB acknowledges previously expressed wishes of the patient,[48,49] there is no reference to this article in Article 17. In addition, while in Article 17 of the ECHRB there is no

[38] ***Council of Europe**, op. cit.*

[39] ***R. I. Freedman**, op. cit*.

[40] ***J. Durham / C. E. Brolan / B. Mukandi**,* "The Convention on the Rights of Persons with Disabilities: A foundation for ethical disability and health research in developing countries", *American journal of public health*, 2014, Vol. 104 (11), pp. 2037.

[41] *Ibid*. pp. 2039.

[42] ***A. M. Duguet / B. Boyer-Beviere**, op. cit*., pp. 616.

[43] ***World Medical Association,** Declaration of Helsinki*, Helsinki, 1964, at article 28, pp. 4.

[44] ***R. I. Freedman**, op. cit*., pp. 137.

[45] ***Council of Europe Steering Committee on Bioethics**, op. cit*., pp. 8.

[46] ***European Parliament and Council of the European Union**, "*Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use", *Official Journal of the European Union*, 2001, Vol. 50, pp. 8-9.

[47] ***S. Lötjönen**,* "Medical research on patients with dementia–the role of advance directives in European legal instruments", *European journal of health law*, 2006, Vol. 13 (3), pp. 246.

[48] *Ibid*., pp. 242

[49] ***Council of Europe*** at footnote 29, *op. cit*., pp. 261.

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reference to a right of expressing opinion for minors, in Article 18 of the Draft Protocol it is stated that 'the opinion of a minor shall be taken into consideration as an increasingly determining factor in proportion to age and degree of maturity'.[50]

One can argue that in absence of conditions as the ones mentioned above, Article 17 is free to interpretation. Thus, depending on the way of interpretation it can either be permissive or prohibitive. However, I would argue that such additional requirements certainlyreassure the presence of an adequate informed consent and protect the subject from the possibility of exploitation, but they can also restrict access to research if the potential participant is unable to fulfil them.In the absence of such provisions, decision-making is facilitated as the process can be completed quicker, the selection of participants is simplifiedespecially because there are no requirements regarding the grade of capacity, as well as, additional assent on the part of the research subjectis not expected. Unless the potential participant objects there is no need to obtain his positive response to carry on with the research.

By limiting such conditions which can function as protective measures regarding the access to research and can reassure an informed consent, the limitation extents to the notion of informed consent and not to the access to research which. Consequently, Article 17 becomes more permissive by omitting to incorporate such protective conditions.Yet, it should be noted that this approach also functions in favour of what has often been argued on behalf of incapacitated individuals in relation to biomedical research.That 'the strict application of the principle of consent would deprive them of the beneficial effects that research carried out for therapeutic purposes might entail for them'.[51] Thus, limited application of the principle of consent, as this is addressed by Article 17, can increase participation of individuals not able to consent.

4. Does Article 17 have any evident prohibitive characteristics?

Certainly, Article 17 does not have an absolute permissive character. This becomes obvious if one considers that it does not include provisions to facilitate research in emergency cases such as the ones considered in Article 29 of the Helsinki Declaration. In Article 29 of the Helsinki Declaration it is stated that for research involving subjects who are

[50] ***Council of Europe Steering Committee on Bioethics****, op. cit.*

[51] ***C. Byk,*** "Medical and Biological Progress and the European Convention on Human Rights", *Medicine and Law*, 1992, Vol. 11, pp. 202.

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physically or mentally incapable of giving consent, in the absence of available legal representative and in cases of emergency research, the study may proceed without informed consent.[52] Evidently, this approach is more permissive than Article 17.

Nevertheless, in addition to the permissive features described above, one can note more details that overall outweigh the prohibitive character of the Article. Initially, it should be mentioned that Article 17 does not define certain groups of incapacitated individuals as more eligible to participate in research. For example, in comparison to the recommendation of the National Commission on the Protection of Human Subject 1978 according to which 'in research on mental disabilities, subjects should be recruited from among non-institutionalised populations wherever possible',[53] Article 17 prevails as more permissive. Albeit, it is justifiable to say that it is too permissive because it does not take into account that certain groups of incapacitated persons, such as institutionalised patients, are more prone to coercion and consequently, to exploitation than others.[54]

Also, Article 17 facilitates access to research since it does not take under consideration difficulties in decision-making that can jeopardise the process of informed consent and restrict the participation to research. In the absence of precautions to avoid the problem of therapeutic misconceptions which often characterise either the participant's or the surrogate's decision,[55] it is possible for the number of incapacitated participants to increase because of fallacious consent referring to treatment instead of research.

In addition, Article 17 does not include any recommendation for the assessment of decision-making in research by investigators such as the IRBs members whose authority is predicted by the NBAC Report in the US.[56] According to the National Institute of Mental Health (US) commentary on the NBAC Report 'not all research projects proposing to involve decisionally impaired persons should be approved by IRBs, and…enabled to participate in research studies'.[57] Such kind of restrictions are not included in Article 17. This fact provides further reasoning on why Article 17is characterized permissive since more impaired persons are likely to participate in biomedical researches in the absence of such restrictions.

[52] ***World Medical Association***, *Declaration of Helsinki,op. cit.*

[53] ***R. I. Freedman***, *op. cit*., pp. 134.

[54] *Ibid.*

[55] ***D. Shore / S. E. Hyman***, "An NIMH commentary on the NBAC report", *Biol Psychiatry*, 1999 Vol. 46, pp. 1014.

[56] *Ibid*. pp. 1013-1016.

[57] *Ibid*. pp. 1015.

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5. Conclusion

In general terms, the permissiveness of Article 17 represents a response to the generic demand for inclusion of people not able to consent in research. Indeed, since the adoption of the Nuremberg Code the involvement of individuals unable to consent in biomedical researches has been significantly increased and official approaches, such as the one of the ECHRB, have promoted this increase.

Although the conditions included in Article 17 of the Convention seem to be prohibitive enough in order to prevent the absolute involvement of incapacitated persons in research, in a closer examination they can be described as less restrictive than those of equivalent guidelines. This can be justified by considering the Article's approach in relation to benefits and risks. While other guidelines explicitly adopt a certain balance between benefits and risks, the conditions of Article 17 in relation to this issue are very simplistic and free to interpretation. The same simplistic approach is adopted in relation to the decision-making which is realistically a difficult process when the potential participant cannot make decision. According to the conditions, the authority is almost entirely deprived from the research subject since no additional considerations in relation to his advance directives or the possibility of his participation in the process of decision making are predicted.

It seems that the conditions of the Article 17 represent basic restrictions without measuring in depth pragmatic difficulties related to the issue of involving incapacitated individuals in research. On one hand, people of this group are depended on their representatives, the law, and the interpretation of Article 17 in order to obtain an opportunity to participate in biomedical research instead of acquiring a chance for their autonomy to be respected and promoted. On the other hand, by omitting additional conditions that would function as gradual steps to make as possible autonomous decision, but would also constitute potential constraints in involving incapacitated persons in research, the value of informed consent is limited in practice in favour of the facilitation of the process concerning the selection of participants. Consequently, in the absence of such additional conditions, the ones that constitutethe Article 17 is justifiable to be characterised as too permissive.

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