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NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES

OPINION ON THE ADDITIONAL PROTOCOL TO THE CONVENTION ON HUMAN RIGHTS AND BIOMEDICINE WITH REGARD TO BIOMEDICAL RESEARCH

(July 2013)

I. GENERAL FRAMEWORK

1. The Directorate-General for External Policies of the Ministry of Foreign Affairs asked for an opinion on the ratification to the Additional Protocol to 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 (CDHBM), regarding the biomedical research, which Portugal signed on 4 February 2005.

2. CNECV had the opportunity to issue Opinions on the matters related to this Protocol. Besides the Opinion on clinical trials with medical products (Opinion 4/CNECV/93 and Analysis Document – Comparison between Legislation related to clinical trials and Ethics Committees and Doctrine set forth by CNECV (Opinion 13/CNECV/95), it has issued an Opinion favourable to the ratification of the Convention on Human Rights and Biomedicine, which was ratified by the Portuguese Parliament on 3 January 2001 (Opinion 30/CNECV/2000).

More recently, CNECV issued Opinion 66/CNECV/2012 on the Draft Bills No. 266/2012 and No.323/2012, about clinical research, which came to result in the Draft Bill No. 146/XII, approved by the Council of Ministers on 9 May 2013, and approved, in general, by the Portuguese Parliament on 14 June 2013.

3. The Additional Protocol to CDHBM with regard to biomedical research was open for signature to the Signatory States of the Strasbourg Convention, on 25 January 2005. However, it hasn't come into force yet "in the international legal order because the necessary five instruments of ratification haven't been deposited, including at least four State members of the European Council".

4. Although it is no longer time for adding suggestions to the document, the current opinion aims to facilitate the comprehension of the ethical relevance of the subject matter of the Protocol and to highlight the values upheld in this document in order to assess its ratification by the Portuguese State.

Although we haven't received a validated translation of the document to the Portuguese language, CNECV's current opinion is based on the official version in English, adopting a free translation of the terms and concepts used in the Additional Protocol, and without prejudice of an ulterior official translation.

II. ETHICAL-LEGAL FRAMEWORK

5. In the international context it is important to mention the Charter of Fundamental Rights of the European Union, especially its article 3 and the UNESCO Universal Declaration on Bioethics and Human Rights. It is also important to mention the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, CIOMS, 2002; and the latest edition of the Declaration of Helsinki (2008).

The European Parliament and the Council of the European Union, when trying to adopt the doctrine of the Declaration of Helsinki for the communitarian legislation, issued Directive 2001/20/CE of 4 April 2001, "with regard to 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».

6. Directive 2001/20/CE was transposed to the Portuguese legislation through *Act No. 46/2004*, of 19 August, which automatically revoked *Decree Law No. 97/94*, of 9 April, about clinical trials.

Presently, it is in progress the legal process for Approval of a Legal Framework for clinical research embodied in the Draft Bill No. 146/XII, which involves the revocation of Act No. 46/2004 of 19 August, e the partial revocation of Act No. 145/2009 of 17 of June, approved by the Council of Ministers on 9 May 2013 and approved, in general, by the Portuguese Parliament on 14/06/2013.

It is relevant to this ongoing discussion the *Proposal for a Regulation of the European Parliament and of the Council with regard to clinical trials on medicinal products for human use* (Proposal of Regulation), issued in July, which repeals Directive 2001/20/CE, subject to the opinion of the European Economic and Social Committee [2012/192 (COD)].

III. ETHICAL RELEVANCE AND VALUES UPHELD IN THE PROTOCOL

7. The protocol develops and fulfils the principles stated in the Convention, in the field of research involving human beings. Considering the importance of the progress of medical sciences through biomedical research, the desire to preserve life and to improve the quality of life and its necessary connection with research in human beings, the Protocol aims to ensure respect for dignity and identity and to assure the protection of fundamental rights and liberties to all human beings involved in any research activity in the field of biomedicine.

8. As general principles, the protocol immediately establishes the priority of the interests and welfare of the human being participating in research over the sole interest of society or science (article 3). This provision considers the protection of the person and its integrity to be paramount, namely when the individual interests may come into conflict with the common interests.

On the other hand, research in human beings may occur when it doesn't exist alternative with comparable effectiveness (article 5); when it has potential for generating a result that directly benefits the participant's health without disproportional risks in comparison to their potential benefits; when there are no direct potential benefits to the participants, the research may only take place in the absence of unacceptable risks or constraints (article 6).

Research on human beings must still be approved by the competent organ and only after an evaluation on its scientific merit, including the assessment of the importance of the research's goals and the multidisciplinary revision on its ethical acceptability, (article 7) and scientific quality (article 8). Each research project must be submitted for assessment by an ethical committee, necessarily independent, in order to assess its ethical acceptability (article 9, No.1), with the purpose to protect dignity, rights, safety and well fare of the research participants (article 9, No.2).

The independence of the ethical committee members must be assured, namely through the demand of a declaration of circumstances that may lead to conflicts of interests (article 10, No.2).

It becomes necessary to inform the persons being asked to participate in a research project, specially referring the issues which the information shall cover (article 13), requiring the informed, free, express, specific and documented consent of the person (article 14), thus acclaiming the principle of autonomy of the human will. As a corollary of this principle, the trial participant may withdraw its consent in any stage of the trial, without consequences, namely in terms of access to health care.

There are special rules, clear and objective, for the protection of people who are not able to consent (article 15) and for the protection of participants in trials on human beings in particular conditions, namely trials during pregnancy or breastfeeding (article 18). There are also rules for safety and support of the trial participants (articles 21 to 24). Data confidentiality is secured (article 25) and it is assured the right to information (article 26) and its way of communication (article 27).

Considering that research is up-to-date and transnationally oriented, the promoters or researchers related to the jurisdiction of a protocol signatory State ought to broaden the principles here stated to research conducted in third countries (article 29).

9. The Protocol conveys to the national laws the regulation of additional conditions for the research in clinical situations of emergency (article 19) and permission and regulation for the participation of people deprived of liberty in the research activity.

It should also be noted that each State may grant research participants a wider protection than it is stipulated in the Additional Protocol.

Each State should also promote the effective implementation of the provisions of the Protocol, ensuring its direct application or even by means of law. In this sense, considering the law in force and the ongoing legislative review, CNECV recommends the necessary framework of the Protocol in the light of the national legal order.

IV. CONCLUSION AND OPINION

Taking into account all of the above and considering its previous opinion, CNECV corroborates the ethical principles and the values conveyed and expresses a favourable opinion to the ratification of the Additional Protocol to the Convention on Human Rights and Biomedicine by the Portuguese State, recommending that the latter ought to be observed by the national legislation.

Lisbon, 17 July 2013.

The President, *Miguel Oliveira da Silva.*

Rapporteur: Counsellor *Rita Lobo Xavier.*

This Opinion was approved in the plenary meeting on 17 July 2013. Besides the President, the following Counsellors were present:

Agostinho Almeida Santos; Ana Sofia Carvalho; Carolino Monteiro; Francisco Carvalho Guerra; Isabel Santos; João Ramalho-Santos; José Germano de Sousa; José Lebre de Freitas; Lucília Nunes; Michel Renaud; Pedro Nunes; Rita Lobo Xavier; Rosalvo Almeida.