



CNECV

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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
CONCERNING TRANSPLANTATION OF ORGANS
AND TISSUES OF HUMAN ORIGIN**

(July 2013)



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I. INTRODUCTION

The Directorate-General for External Policies of the Ministry of Foreign Affairs intends to resume the process of ratification, for Portugal, of 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, concerning transplantation of organs and tissues of human origin.

Thus, it has been requested to the National Council of Ethics for the Life Sciences (CNECV) to express an opinion on this Additional Protocol.

II. BACKGROUND AND LEGAL FRAMEWORK

The CNECV issued an Opinion on the quoted documents in previous occasions, namely:

- Opinion 30/CNECV/2000, in favour of the ratification of the Convention on Human Rights and Biomedicine;
- and Opinion 41/CNECV/2003 – Opinion on the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin, in which it also expressed a favourable opinion to the ratification of the Additional Protocol.

The time lag elapsed, the progress of medical science in this field, and the amendments occurred to the Portuguese legislation in this area justify CNECV's second opinion on a matter previously revised.

At the time of issue of the above mentioned Opinion 41/CNECV/2003, the current Portuguese law about transplantations (Act No. 12/93, of 22 April, which is still in force, although amended and reissued by Act No. 22/2007, of 29 June), aimed to partially transpose to the national legal order the Directive No. 2004/23/CE, of the European Parliament and Council of 31 de March.



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CNECV issued its Opinion 50/CNECV/2007 – Opinion on the Draft Bill No.65/X – Amendment to Act No. 12/93, of 22 April - «Removal and Transplantation of organs and tissues of human origin » (50/CNECV/2006), favourable to this act, to expand the group of potential donors concerning non-regenerable organs. Finally, Act No. 36/2013, of 12 June revoked No. 3 and No. 4, article 3.º of Act No. 12/93, of 22 de April.

In the context of transplantations, CNECV has also issued Opinion 65/2012 – Opinion on the Quality and safety legal framework for the donation, removal, testing, processing, preservation, storage, distribution and application of organs of human origin. The opinion was in general consensual with the bill that generated this act. It aimed to “establish the regime of guarantee of quality and safety of organs of human origin for transplantation in the human body, in order to assure a high level of protection of human health, surpassing the Directive No. 2010/53/UE, of the European Parliament and Council, of 7 July, regarding regulations of quality and safety of the human organs for transplantation”.

It should also be noted that the deadline for suggesting reformulation or amendment of the articles in the Additional Protocol was surpassed, as occurred in the last opinion of this Council. In fact, this Protocol was approved by the Committee of Ministers on 8 November, 2001, in accordance with the Portuguese Representation. It was open for signature to the Convention Signatory States on 24 January 2002, coming into force on 1 May 2006. Therefore, CNECV’s Opinion will aim, as before, to provide the comprehension of the ethical aspects in question in this document, in the light of the actual context of transplantation of organs and tissues of human origin.

In Opinion 41/2003, CNECV highlighted the ethical relevance of the object of the Additional Protocol and the values obtained from it. The Protocol’s goal is to protect the dignity, identity and integrity of all human beings with regard to transplantation of organs and tissues of human origin, establishing regulations for donation by living donors and imposing the rule of informing the donor and obtaining his consent – a free, informed and specific consent. It also establishes special rules, clear and objective, for the protection of living donors who do not have the capacity to consent. It also determines the principles of non-commercialization and confidentiality.



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Since then, CNECV has had other opportunities to express opinions on matters related to the above mentioned Additional Protocol, regarding the amendment of the respective national legislation.

The evolution verified in the last ten years has confirmed the importance of the Additional Protocol on transplantations with regard to the proper protection to human beings, the validity of its ethical framing and the timeliness of the ethical issues stated. Therefore, previous Council's opinions maintain its relevance and timeliness.

III. CONCLUSION AND OPINION

Taking the above mentioned into account and considering the previous opinion, the CNECV retains its opinion favourable to the ratification of the Additional Protocol to the Convention on Human Rights and Biomedicine with regard to the transplantation of organs and tissues of human origin.

Lisbon, 17 July 2013

The President, *Miguel Oliveira da Silva*.

Rapporteur: Counsellor *Rita Lobo Xavier*.

This Opinion was approved in the plenary meeting of 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.