

CYPRUSⁱ

a) Laws governing clinical trials

- K.Δ.Π. 318/2006 *Regulatory Administrative Act on Medicinal Products for Human Use (Quality Control, Purchase and Prices)*, amending L. 70(I)/2001, 83(I)/2002, 35(I)/2004, 78(I)/2004, 100(I)/2004, 263(I)/2004, 13(I)/2005, 28(I)/2005, 97(I)/2005, 122(I)/2005, 20(I)/2006, 75(I)/2006 and 104(I)/2006.
- L. 1(I)/2005 *Law on the Safeguarding And Protection of Patients' Rights, 2004*
- K.Δ.Π. 175/2005 *Regulatory Administrative Act for the Establishment of Ethics Committees Reviewing Biomedical Research on Human Subjects*, decree and appendices supplementing L. 150(I)/2001 and enacted 31st March 2005 based on the operational guidelines of the World Health Organisation (WHO).
- K.Δ.Π. 452/2004 *Regulatory Administrative Act on Medicinal Products for Human Use (Quality Control, Purchase and Prices)*, amending L. 70(I)/2001, 83(I)/2002, 35(I)/2004
- L. 150(I)/2001 *Law providing for the Establishing and Function of the National Bioethics Committee*, which was enacted in December 2001.
- L. 31(III)/2001 *Law Adopting the Oviedo Convention on Human Rights and Biomedicine*.

b) Ad hoc provisions for paediatric trials

- Article 4 Directive 2001/20/EC implemented
- Usually both parents must give the consent. Assent is not mandatory

c) Ethics Committees / National Competent Authority

- CNBC (Cyprus National Bioethics Committee)
- Department of Medical and Public health Services of the Ministry of Health (Competent Authority)

d) Paper or electronic application / existence of a national website

Paper submission. No national databases.

e) Procedures for compiling the EU CTA form (e.g. from EudraCT or from the national database)

The EU CTA form to be completed from EudraCT.

f) Requested documents to be submitted

Documents to be submitted are available [here](#). Specific templates for informed consent, CTA form, amendments are available.

TEDDY Network is coordinated by:

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SOURCES:

- General legal resource: http://www.mof.gov.cy/mof/gpo/gpo.nsf/dmlgazette_archive_gr
- Bioethics Committee, governing laws:
<http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/C68D8A0952500F56C22571C9002A6917?OpenDocument>
- Bioethics Committee, regulatory administrative acts:
<http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/All/E720470107A70ACDC225754600592F2C?OpenDocument>
- Pharmaceutical Services (under heading Legislation, but documents are only displayed for the Greek version of the web site):
http://www.moh.gov.cy/moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument

ⁱ *This document has been prepared by TEDDY Network as part of its research activity. Information have been derived by questionnaires filled in by researchers and from official national databases where available. It does not replace the official data that can be accessed directly or are provided at the experimental site . The material cannot be distributed nor re-utilised without acquiring a specific preliminary consent from the Network.*

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