



EDCTP Guidelines on Ethics

Regulatory authorities require that all new investigational medicinal products intended for use in humans must be shown to be safe, effective and of the highest quality.

All studies that are funded by EDCTP must be run in accordance with the standards and codes of conduct accepted by the **International Conference on Harmonisation (ICH)** guidelines and in compliance with the local ethics requirements of the countries where these studies are to be conducted.

In accordance to these guidelines, all clinical studies have to be submitted to and approved by an independent Ethics Committee that complies with the World Health Organisation Operational Guidelines for Ethics Committees that Review Biomedical Research (TDR/PRD/ETHICS/2000.1).

"Compliance with these guidelines helps to ensure that rights, safety and well-being of research participants are promoted and that the results of the investigations are credible". The role of the Ethics Committee is to safeguard the interest of volunteers taking part in studies.

National Legislation

Participants in EDCTP funded projects must conform to current legislation and regulations in the countries where the research will be carried out, as well as in the country where the PI is located. Where required by national legislation or rules, participants must seek the approval of the relevant ethics committees prior to the start of the research activities that raise ethical issues.

EU Legislation

In addition to compliance with national legislation, applications must conform to the following EU legislations:

- [The Charter of Fundamental Rights of the EU](#)
- [The Directive 2001/20/EC](#) of the EU Clinical Trials Directive
- [Directive 2004/23/EC](#) of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- [Directive 95/46/EC](#) of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Council Directive [83/570/EEC](#) of 26 October 1983 amending Directives [65/65/EEC](#), [75/318/EEC](#) and [75/319/EEC](#) on the approximation laid down by law, regulation or administrative action relating to proprietary medicinal products
- [Directive 98/44/EC](#) of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
- Directive [98/81/EC](#) of 26 October 1998 on the contained use of genetically modified micro-organisms
- [Directive 2001/18/EC](#) of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC
- [Directive 2001/20/EC](#) 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.
- The EU directive of Biobanks
- The [FP6 Ethical Rules](#), Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 which applies to all research carried out under the FP6



International Conventions and Declarations

Applicants should also respect the following international conventions and declarations:

- [Helsinki Declaration](#) in its latest version
- [Convention of the Council of Europe on Human Rights and Biomedicine](#) signed in Oviedo on 4 April 1997, and the Additional Protocol on Biomedical Research (January 2005)
- Council of Europe: Recommendation [Rec\(2006\)4](#) on research on biological materials of human origin and [explanatory note](#) published February 2006 on the use of human tissue for research.
- [UN Convention on the Rights of the Child](#)
- [Universal Declaration on the human genome and human rights](#) adopted by UNESCO

All EDCTP funded clinical trials should be registered in an official clinical trials registry

Further information on ethics requirements and rules are given at the science and ethics website at: http://europa.eu.int/comm/research/science-society/ethics/ethics_en.html.

Abbreviations:

EU = European Union
EC = European Commission
FDA= Food and Drugs Administration
FP6 = EU Sixth Framework Programme
PI= Principle Investigator