

IPA Guidelines on Declaration form for multilateral and multinationals

Current scientific and technological evolution in the field of medicine is associated with the growing importance of the role of universal ethical values concerning the protection of human rights and dignity. This tendency becomes particularly essential in the course of deep social and cultural changes that have been happening during the last decades all over the world. Global changes have brought new policies in the field of ethics and bioethics along with initiatives and consolidating activities in law making, education, and creation of the system for the ethical review and international cooperation. Health professionals, lawyers, social scientists, researchers and others concerned with human rights need to join to improve individual and community health and well-being by protecting and promoting human rights. In doing so, it appears to be of tremendous importance that officially each of the countries declares adherence to all major norms and principles stipulated by international and legal documents, such as

- the *Nuremberg Code* of 1947,
- the *Declaration of Helsinki of the World Medical Association (WMA) in 1964* with amendements *International Ethical Guidelines for Biomedical Research Involving Human Subjects* developed by CIOMS and WHO in 1982 and amended in 1993 and 2000,
- *International Guidelines for Ethical Review of Epidemiological Studies*, CIOMS, 1991,
- *Guidelines for Good Clinical Practice (ICH GCP)*, 1996;
- *Operational Guidelines for Ethics Committees that Review Biomedical Research* (WHO, 2000) with additional document of 2002,
- *Convention for the Protection of Human Rights and Dignity with Regard to the Application of Biology and Medicine: Convention of Human Rights and Biomedicine* (Council of Europe, 1997) and adopted in addition there of *Additional Protocols* including *the Protocol on Biomedical Research, Universal Declaration on Bioethics and Human Rights* (UNESCO, 2005),
- *Universal Declaration on the Human Genome and Human Rights* (UNESCO, 1997),
- *International Declaration on Human Genetic Data* (UNESCO, 2003) and
- a number of other documents

which current total list includes more than 150 publications.

The international enactments mentioned above became a basis for legal regulation of biomedical research and their ethical review in the majority of developed countries (detailed analysis of legal participation of a particular country in any of international documents – recommendation influence, ratification, adaptation to national legislation, etc. can be found in the given document)

A crucial issue emphasizing profound importance of international documents regulating this sphere

is a fact of priority of international laws approved by a great number of the countries. International cooperation in the field of bioethics is implemented also through formation of regional programs and centres of bioethics and research ethics with the involvement of international organizations being leaders in this field. A convincing example of such cooperation is a setup of national committees of bioethics with the support of the UNESCO in some of the Commonwealth countries and planned scientific and educational activities of the UNESCO office, partly within the framework of the WHO project, *the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)*.

INTERNATIONAL ORGANIZATIONS AND MULTILATERAL, MULTINATIONAL DECLARATIONS ON HUMAN RIGHTS

- **UNESCO:** Report on Genetic Screening and Testing by David Shapiro, 1994
Web address: http://portal.unesco.org/shs/en/file_download.php/bf5fa8468519b693df4bcd609c03b384GeneticTestingCIB2_en.pdf
- **UNESCO:** International Declaration on Human Genetic Data. 2004
<http://www.unesco.org/shs/ethics>
- **WHO:** Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services, WHO Human Genetics Programme, 1998
Web address: <http://www.who.int/genomics/publications/en/ethicalguidelines1998.pdf>
- **OECD Programme on Biotechnology: Genetic Testing – guidelines for millennium**
Web address: <http://213.253.134.29/oecd/pdfs/browseit/9300051E.PDF>

EUROPEAN ORGANIZATIONS :

- **Council of Europe:** Recommendation No. R(92) 3 of the Committee of Ministers to Member States on Genetic Testing and Screening for Health Care Purposes, 1992
Draft Recommendation Rec (2009)
Web address: [http://www.coe.int/T/E/Social_Cohesion/Health/Recommendations/Rec\(1992\)03.asp#TopOfPage](http://www.coe.int/T/E/Social_Cohesion/Health/Recommendations/Rec(1992)03.asp#TopOfPage)
- **European Commission:** 25 recommendations on the ethical, legal and social implications of genetic testing by an expert group of European Commission, 2004
Web address: http://europa.eu.int/comm/research/conferences/2004/genetic/pdf/recommendations_en.pdf
- **European Commission European Group on Ethics in Science and New Technologies (EGE):** Opinion No 6 Ethical Aspects of Prenatal Diagnosis, 1999
Web address: http://europa.eu.int/comm/european_group_ethics/gaieb/en/opinion6.pdf

INTERNATIONAL PROFESSIONAL ORGANIZATIONS: (DEALING WITH ETHICAL ISSUES)

- **World Medical Association:** Statement on genetic counselling and genetic engineering, 1987
Web address: <http://www.wma.net/e/policy/c15.htm>
- **World Medical Association:** Declaration of the human genome project, 1992
Web address: <http://www.wma.net/e/policy/g6.htm>
- **Human Genome Organisation:** Statement on the Principled Conduct of Genetics Research. HUGO ethical, legal, and social issues committee report to HUGO Council, 1996

Web address: <http://www.gene.ucl.ac.uk/hugo/conduct.htm>

- **International Federation of Gynecology and Obstetrics (FIGO):** Recommendations on Ethical Issues in Obstetrics and Gynecology by the FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health, 2003
Web address: http://www.figo.org/content/PDF/ethics-guidelines-text_2003.pdf

EUROPEAN PROFESSIONAL ORGANIZATIONS :

- **European Society of Human Genetics (ESHG):** Provision of genetic services in Europe: current practices and issues policy, 2003
Web address: <http://www.eshg.org/PPPC.htm>
- **The European Association for Bioindustries (EuropaBio):** Human Medical Genetic Testing. A EuropaBio Position Paper, 2004
Web address: http://www.europabio.org/articles/article_317_EN.doc
- **EURORDIS – European Organisation for Rare Diseases:** Guidelines for organisations providing information on rare diseases, 2004
Web address: http://www.eurordis.org/IMG/pdf/pard3_guidelines_leaflet.pdf

PROFESSIONAL ORGANIZATIONS ON OTHER CONTINENTS:

- **American Society of Human Genetics (ASHG):** Paper on Professional Disclosure of Familial Genetic Information, 1998
Web address: <http://genetics.faseb.org/genetics/ashg/pubs/policy/pol-29.htm>
- **National Society of Genetic Counselors (USA):** Code of Ethics
Web address: http://www.nsgc.org/about/code_of_ethics.asp
- **National Society of Genetic Counselors:** Genetic cancer risk assessment and counseling: Recommendations of the National Society of Genetic Counselors, 2004
Web address: http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=5274&nbr=3601
- **Society of Surgical Oncology:** Statement on Genetic Testing for Cancer Susceptibility, 1999
Web address: <http://www.annalsurgicaloncology.org/cgi/reprint/6/5/507>
- **American Society of Clinical Oncology:** Policy Statement Update: Genetic Testing for Cancer Susceptibility, 2003
Web address: <http://www.jco.org/cgi/content/abstract/JCO.2003.03.189v1?ck=nck>
- **Human Genetic Society of Australasia (HGSA):** Guidelines for the practice of genetic counselling, 1999
Web address: <http://www.hgsa.com.au/>
- **Human Genetic Society of Australasia (HGSA):** DNA Presymptomatic and predictive testing for genetic disorders, 2002
Web address:
- **Human Genetic Society of Australasia (HGSA):** Child testing policy
Web address: <http://www.hgsa.com.au/>

Related websites

National Center for Biotechnology Information: www.ncbi.nlm.nih.gov

GDB: the Human Genome Database: www.gdb.org

EuroGenetest Network of Excellence: www.eurogentest.org