

**PAUTAS ÉTICAS INTERNACIONALES SOBRE
INVESTIGACIÓN EN SERES HUMANOS***
(SELECCIÓN DE EDUARDO RODRÍGUEZ YUNTA)

INTERGOVERNMENTAL ORGANIZATIONS

COUNCIL OF EUROPE

COMMITTEE OF MINISTERS

- Recommendation Concerning Medical Research on Human Beings (1990)
- Convention on Human Rights and Biomedicine (1997)
- Recommendation on the Protection of Medical Data (1997)
- Additional Protocol on the Prohibition of Cloning Human Beings (1997)
- Protocol on the Prohibition of Cloning Human Beings (1998)

PARLIAMENTARY ASSEMBLY

- Recommendation on Genetic Engineering (1982)
- Recommendation on the Supply and Utilisation of Human Blood and Blood Products (1984)
- Recommendation on the Use of Human Embryos and Foetuses for Diagnostic, Therapeutic, Scientific, Industrial and Commercial Purposes (1986)
- Recommendation on the Use of Human Embryos and Foetuses for Research Purposes (1989)
- Order Nº 534 (1997) on Research and the Cloning of Human Beings (1997)
- Opinion Nº 202 (1997) on the Draft Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (1997)

STEERING COMMITTEE ON BIOETHICS (CDBI) (Documents in Preparation)

- Draft Protocol on Biomedical Research (2000?)
- Draft Protocol on the Protection of the Human Embryo and the Foetus (2002?)
- Draft Protocol on Problems Relating to Human Genetics (2002?)

EUROPEAN UNION

EUROPEAN COUNCIL

- European Council Declaration on Banning the Cloning of Human Beings (1997)

EUROPEAN COMMISSION

- Good Clinical Practice in the Conduct of Clinical Trials on Medicinal Products for Human Use (1991)

EUROPEAN PARLIAMENT

- Resolution on European Harmonisation of Medicoethical Questions (1988)

* Fluss S. *International Guidelines on Bioethics*. Geneva: Supplement to the EFGCP News; December 1999.

- Resolution on the Ethical and Legal Problems of Genetic Engineering (1989)
- Resolution on Cloning of the Human Embryo (1993)
- Resolution on Cloning (1997)
- Resolution on Human Cloning (1998)
- Resolution on the Development of Public Health Policy in the European Community (1999)

GROUP OF ADVISERS ON THE ETHICAL IMPLICATIONS OF BIOTECHNOLOGY

- Opinion on Ethical Questions Arising from the Commission Proposal for a Council Directive on Legal Protection for Biotechnological Inventions (1993)
- Opinion on the Ethical Implications of Gene Therapy (1994)
- Opinion on Ethical Aspects of Patenting Inventions Involving Elements of Human Origin (1996)
- Opinion on Ethical Aspects of Cloning Techniques (1997)
- Opinion on the Ethical Aspects of the 5th Research Framework Programme (1997)

EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES

- Ethical Aspects of Human Tissue Banking (1998)
- Ethical Aspects of Research Involving the Use of Human Embryos (1998)
- Ethical Aspects of Research Involving the Use of Human Embryos in the Content of the Fifth Framework Programme (1998)

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE (ICH)

- Guideline for Good Clinical Practice (ICH Harmonised Tripartite Guideline) (1997)

NORDIC COUNCIL ON MEDICINES

- Nordic Guidelines on Good Clinical Trial Practice (1989)

ORGANIZATION OF AFRICAN UNITY

- Resolution on Bioethics (1996)

UNAIDS (JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS)

- Draft Guidance Document on Ethical Considerations in HIV Preventive Vaccines Research (2000?)

UNITED NATIONS

- Resolution XI (Human rights and scientific and technological developments), adopted on 12 May 1968 by the International Conference on Human Rights (Teheran, 22 April - 13 May 1968)

GENERAL ASSEMBLY

- Resolution 2450 (XXIII) on “Human rights and scientific and technological developments”, adopted on 19 December 1968

- Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care (1991)
- Resolution 53/152 on “The Human Genome and Human Rights” (1998)

COMMISSION ON HUMAN RIGHTS

- Resolution on Non-Discrimination in the Field of Health (1989)
- Resolution on Human Rights and Bioethics (1993)
- Resolution on Human Rights and Bioethics (1997)
- Decision on Human Rights and Scientific and Technological Developments (1998)
- Resolution on the Rights of the Child (1998)
- Resolution on Human Rights and Forensic Medicine (1998)
- Resolution on Human Rights and Bioethics (1999)
- Resolution on Human Rights and HIV/AIDS (1999)

UNESCO

- Recommendation on the Status of Scientific Researchers (1974)
- Universal Declaration on the Human Genome and Human Rights (adopted on 11 November 1997)
- Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights (1999)

UNITED NATIONS POPULATION FUND (UNFPA)

- Declaration of Ethical Principles, adopted by the Roundtable on Ethics, Population and Reproductive Health (New York, 8-10 March 1994)

WORLD HEALTH ORGANIZATION

- Ethical Criteria for Medicinal Drug Promotion (1988)
- Ethical Guidelines for Epidemiological Investigations (issued by the Scientific Working Group on Epidemiology of the Special Programme for Research and Training in Tropical Diseases) (1989)
- Guidelines for the Establishment of Scientific and Ethical Review Bodies (issued by the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction) (1994)
- Guidelines for Research on Reproductive Health Involving Adolescents (issued by the UNDP/UNFPA /WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction) (1994)
- Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products (1995)
- Guidelines for Clinical Research on Acupuncture (WHO Regional Office for the Western Pacific) (1995)
- Resolution on Cloning in Human Reproduction (adopted by the Fiftieth World Health Assembly) (1997)
- Statement of WHO Expert Advisory Group on Ethical Issues in Medical Genetics (1998)
- Resolution on Ethical, Scientific and Social Implications of Cloning in Human Health (adopted by the Fifty-first World Health Assembly) (1998)

- Proposed International Guidelines on Ethical Issues in Medical Genetics and Genetic Services (1998)
- Draft Operational Guidelines for Ethics Committees Reviewing Biomedical Research (2000?)

NON-GOVERNMENTAL ORGANIZATIONS

AMNESTY INTERNATIONAL

- Principles for the Medical Investigation of Torture and Other Cruel, Inhuman or Degrading Treatment (1996)

COMMONWEALTH MEDICAL ASSOCIATION

- Guiding Principles on Medical Ethics and Human Rights (1995)
- Declaration on the Role of Medical Ethics and a Woman's Right to Health, Including Sexual and Reproductive Health (1997)

COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS)

- The Declaration of Inuyama on Human Genome Mapping, Genetic Screening and Gene Therapy (1990)
- International Guidelines for Ethical Review of Epidemiological Studies (1991)
- International Ethical Guidelines for Biomedical Research Involving Human Subjects (1993 and 2002)
- The Declaration of Ixtapa: A Global Agenda for Bioethics (1994)

EUROPEAN ALLIANCE OF GENETIC SUPPORT GROUPS

- Ethical Code (1996)
- Briefing Paper on Cloning (1997)

EUROPEAN ASSOCIATION FOR BIOINDUSTRIES (EUROPABIO)

- Core Ethical Values (1998)

EUROPEAN ASSOCIATION OF TISSUE BANKS

- Ethical Code (1994)

EUROPEAN FORUM FOR GOOD CLINICAL PRACTICE

- Guidelines and Recommendations for European Ethics Committees (1995; 1997)

EUROPEAN MEDICAL RESEARCH COUNCILS

- Recommendations on Human In-Vitro Fertilisation and Embryo Transfer (1983)
- Recommendations on Gene Therapy in Man (1988)

EUROPEAN SOCIETY OF HUMAN REPRODUCTION AND EMBRYOLOGY

- Declaration (Voluntary Moratorium on Cloning Human Beings) (1998)

***FIGO (INTERNATIONAL FEDERATION OF GYNECOLOGY AND OBSTETRICS)
COMMITTEE FOR THE STUDY OF ETHICAL ASPECTS OF HUMAN REPRODUCTION***

- Recommendations on Research on Pre-embryos (1990)
- Recommendations on Ethical Guidelines Regarding Altering Genes in Humans (1997)
- Recommendations on Patenting Human Genes (1997)
- Recommendations on Cloning in Human Reproduction (1997)

HUMAN GENOME ORGANISATION

- Statement on the Principled Conduct of Genetics Research (1996)
- Statement on DNA Sampling Control and Access (1998)
- Statement on Cloning (1999)

INTERNATIONAL BAR ASSOCIATION

- Draft International Convention on the Human Genome (2000?)

INTERNATIONAL MEDICAL PARLIAMENTARIANS ORGANIZATION

- London Statement on Medical Ethics and Human Rights (1995)

INTERNATIONAL UNION OF PSYCHOLOGICAL SCIENCE

- Statement of the IUPsyS [on professional standards of ethics in the practice of psychology] (1996)

INTER-PARLIAMENTARY UNION

- Resolution on Bioethics and its Implications Worldwide for Human Rights Protection (1995)

ISLAMIC ORGANIZATION FOR MEDICAL SCIENCES

- Islamic Code of Medical Ethics (1981)

***NETWORK FOR EUROPEAN CNS TRANSPLANTATION AND RESTORATION
(NÉCTAR)***

- Ethical Guidelines for the Use of Human Embryonic or Fetal Tissue for Experimental and Clinical Neurotransplantation and Research (1994)

STANDING COMMITTEE OF EUROPEAN DOCTORS (CP)

- First Statement on Storage of Medical Data in Computer Banks (1982)
- Statement on Medical Secrecy in Community Law (1984)
- Analysis of the human genome (1989)
- Statement on limitation of health resources and medical ethics (1993)

WORLD FEDERATION FOR MENTAL HEALTH

- Declaration of Human Rights and Mental Health (1989)

WORLD MEDICAL ASSOCIATION

- International Code of Medical Ethics (1949; 1983)

- Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Subjects (1964; 1975; 1983; 1989; 1996)
- Statement on Genetic Counselling and Genetic Engineering (1987)
- Statement on the Use and Misuse of Psychotropic Drugs (1975; 1983)
- Declaration on the Human Genome Project (1992)
- Statement on Patient Advocacy and Confidentiality (1993)
- Statement on Professional Responsibility for Standards of Medical Care (1996)

GOVERNMENTAL ENTITY

HOLYSEE

- Encyclical Letter on the Value and Inviolability of Human Life (*Evangelium Vitae*) (1995)

CONGREGATION FOR THE DOCTRINE OF THE FAITH

- Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation (*Donum Vitae*) (1987)

PONTIFICAL ACADEMY FOR LIFE

- Reflections on Cloning (1997)

MISCELLANEOUS INTERNATIONAL TEXTS

- Nuremberg Code (adopted by the US Tribunal on 19 July 1947)
- Conclusions and Recommendations of the International Symposium on the Effects on Human Rights of Recent Advances in Science and Technology (Barcelona, 25-28 March 1985). Organized by UNESCO and the International Social Sciences Council
- Summary Report of the International Summit Conference on Bioethics (Ottawa) (1987)
- Ethical Guidelines for Human Reproduction Research in the Muslim World (1992)
- Bilbao Declaration. Adopted by the International Workshop on Legal Aspects of the Human Genome Project (Bilbao, Spain, 24-26 May 1993)
- Fukui Statement on International Bioethics. Adopted at the Third International Bioethics Seminar (Fukui, Japan, 19-21 November 1995)
- Common Position on Ethics of Biomedical Research and the Biopharmaceutical Industry of the Representatives of the European Patients' Organizations (Brussels, 10 January 1994)
- Statement on Human Gene Therapy adopted by the International Symposium on Human Gene Therapy (Inuyama and Nagoya, Japan, 1995)
- Model Ethical Code for Psychiatrists (draft version developed by a Working Group of the Network of Reformers in Psychiatry at its Fourth Meeting, Madrid, 29-31 August 1996)
- Declaration of Manzanillo. Adopted by the 1st Latin American Meeting on Bioethics and the Human Genome (Manzanillo, Colima State, México, 9-12 October 1996)
- Proposed Model Ethical Protocol for Collecting DNA Samples. Prepared by the North American Regional Committee of the Human Genome Diversity Project (1998?)
- New Delhi Charter on Global Drugs Law. Adopted by the International Conference on Global Drugs Law (New Delhi, 28 February-3 March 1997)
- Recommendations (notably on human cloning) of the 9th Fiqh [Islamic Jurisprudence] -

Medical Seminar, organised jointly by the Islamic Organization for Medical Sciences, WHO (Eastern Mediterranean Regional Office), the Arab Educational, Scientific and Cultural Organization, and the Fiqh Academy of the Organization of the Islamic Conference (Casablanca, 14-17 June 1997)

- The Uganda Declaration of 1997. Adopted on 31 August 1997 at the 1st International Federation of Medical Students' Associations Training Workshop on Human Rights and Medicine (Kampala and Mbarara, Uganda, 23 August-1 September 1997)
- Declaration in Defense of Cloning and the Integrity of Scientific Research. Signed by Humanist Laureates of the International Academy of Humanism (1997)
- Deontology and Good Practices in Epidemiology. Recommendations of the Association of French-speaking Epidemiologists (ADELF) (1998)
- The Barcelona Declaration on Policy Proposals to the European Commission on Basic Ethical Principles in Bioethics and Biolaw (adopted in November 1998 by Partners in the BIOMED II Project)
- Declaration on Human Cloning. Adopted by the participants at the Journées Internationales de Bioéthique (Yaoundé, Cameroon, 8-10 March 1999)