

Genetic testing is subject to a wide range of national and international guidance: guidelines, recommendations, declarations, reports and regulations. The international guidance has formed the basis for the national guidance adopted in many countries. One of the objectives of Unit 4 (WP4.1) is to make an inventory of international guidance. This list will be updated continuously in the future. Suggestions are always welcome.

Sincerely,

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### **International guidance from official international documents**

<b>Guideline developer</b>	<b>Year</b>	<b>Title</b>	<b>Country</b>
1. Council of Europe: Parlementary assembly	1982	Recommendation 934 (1982) on genetic engineering	Europe
2. Council of Europe: Committee of Ministers	1984	Recommendation no. R (84) 16 concerning notification of work involving recombinant deoxyribonucleic acid (DNA)	Europe
3. Council of Europe: Parlementary assembly	1986	Recommendation 1046 (1986) on the use of human embryos and fetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes	Europe
4. Council of Europe: Parlementary assembly	1989	Recommendation 1100 (1989) on the use of human embryos and fetuses in scientific research	Europe
5. Council of Europe: Committee of Ministers	1990	Recommendation No. R (90) 13 on prenatal genetic screening, prenatal genetic diagnosis and associated genetic counselling	Europe
6. Council of Europe: Committee of Ministers	1992	Recommendation No. R (92) 3 on genetic testing and screening for health care purposes	Europe
7. Council of Europe: Committee of Ministers	1992	Recommendation No. R (92) 1 on the use of analysis of deoxyribonucleic acid within the framework of the criminal justice system	Europe
8. Council of Europe: Committee of Ministers	1994	Recommendation No. R (94) 11 on screening as a tool of preventive medicine	Europe
9. Council of Europe: Parlementary assembly	1994	Recommendation 1240 (1994) on the protection and patentability of material of human origin	Europe
10. Council of Europe	1997	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	Europe
11. Unesco: general conference	1997	Universal declaration on the human genome and human rights	International
12. Council of Europe	1998	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, on the prohibition of	

		cloning human being	
13. Council of Europe: Parliamentary assembly	2001	Recommendation 1512 (2001) on protection of the human genome by the council of Europe	Europe
14. Council of Europe	2002	Additional protocol to the convention for the protection of human rights and biomedicine concerning transplantation of organs and tissues of human origin	Europe
15. Unesco: general conference	2003	International declaration on human genetic data	International
16. European Parliament and of the Council of Europe	2004	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	Europe

### **Guidelines and position papers about genetic testing**

<b>Guideline developer</b>	<b>Year</b>	<b>Title</b>	<b>Country</b>
17. World Medical Association	1987	World Medical Association Statement on Genetic Counseling and Genetic Engineering	International
18. German Society of Human Genetics	1989	Statement of the German Society of Human Genetics	Germany
19. National Consultative Ethics Committee for Health and Life Science	1989	Opinion concerning the dissemination of DNA analysis identification techniques (genetic fingerprinting)	France
20. Council for International Organizations of Medical Sciences	1990	The declaration of Inuyama. Human Genome Mapping, Genetic Screening and Gene Therapy	International
21. German Society of Human Genetics	1991	Statement on postnatal predictive genetic diagnosis	Germany
22. National Consultative Ethics Committee for Health and Life Science	1992	N. 30 Ethical issues raised by mandatory genetic testing for female participants in the albertville games	France
23. World Medical Association	1992	World Medical Association Declaration on the Human Genome Project	International
24. National	1993	N. 33 Opinion concerning the identification of patients suffering from glaucoma in France	France

	Consultative Ethics Committee for Health and Life Science		and on chromosomal location of the causative gene or genes	
25.	Swiss Academy of Medical Sciences	1993	Medical-ethical guidelines for genetic investigations in humans	Switzerland
26.	International Huntington Association and the World Federation of Neurology	1994	Guidelines for the molecular genetics predictive test in Huntington's disease	International
27.	Japan Society of Human Genetics	1995	Guidelines for genetic testing, using DNA analysis	Japan
28.	German Society of Human Genetics	1996	Position paper of the German Society of Human Genetics	Germany
29.	American Society of Human Genetics: Social Issues Subcommittee on Familial Disclosure	1998	Professional disclosure of familial genetic information	USA
30.	Genetic Interest Group	1998	Confidentiality and medical genetics	UK
31.	Genetic Interest Group	1998	Guidelines for genetic services	UK
32.	WHO	1998	Proposed international guidelines on ethical issues in medical genetics and genetic services	International
33.	WHO	1998	Statement of WHO expert advisory group on ethical issues in medical genetics	International
34.	American College of Medical Genetics: Social ethical and legal issues committee	1999	Duty to recontact	USA
35.	Human Genetics Society of Australia	1999	Privacy implications of genetic testing	Australia
36.	National Bioethics Committee	1999	Bioethical guidelines for genetic testing	Italy
37.	Society of surgical	1999	Statement on genetic testing for cancer susceptibility	USA

oncology				
38. Disabled peoples' International Europe	2000	The right to live and be different		International
39. European Society of Human Genetics	2000	Population genetic screening programmes: technical, social and ethical issues		Europe
40. International Society of Nurses in Genetics	2000	Informed decision-making and consent: the role of nursing		International
41. Japan Society of Human Genetics	2000	Guidelines for genetic testing		Japan
42. National Society of Genetic Counsellors	2000	Code of Ethics		USA
43. American College of Medical Genetics	2001	Points to consider in preventing unfair discrimination based on genetic disease risk		USA
44. American Geriatrics Society: Ethics Committee	2001	Genetic testing for late-onset Alzheimer's Disease		USA
45. European Society of Human Genetics	2001	Provision of genetic services in Europe: current practices and issues		Europe
46. International Society of Nurses in Genetics	2001	Privacy and confidentiality of genetic information: the role of the nurse		International
47. Japan Society of Human Genetics	2001	Guidelines for genetic testing		Japan
48. Human Genetics Society of Australia	2002	DNA presymptomatic and predictive testing for genetic disorders		Australia
49. Human Genetics Society of Australia	2002	Role of the Clinical Geneticist		Australia
50. International Society of Nurses in Genetics	2002	Genetic counseling for vulnerable populations: the role of nursing		International
51. National Bioethics Commission	2002	Recommendation on the collection and use of genetic data		Greece
52. European Patient Groups	2002	Joint statement on The European Commission's proposal to amend the Directive on Community Code relating to Products for Human use (Directive 92/28/EEC) - Articles 86 to 100		International

53. Belgian Society of Human Genetics	2003	Guidelines for predictive genetic testing for late onset disorders	Belgium
54. Council of Europe: working party on human genetics	2003	Working document on the applications of genetics for health purposes	Europe
55. National Consultative Ethics Committee for Health and Life Science	2003	N. 76 Regarding the obligation to disclose genetic information of concern to the family in the event of medical necessity	France
56. WHO: report of consultants to WHO	2003	Review of ethical issues in medical genetics	International
57. American society of clinical oncology	2003	Policy statement update: genetic testing for cancer susceptibility	USA
58. EuropaBio	2004	Human Medical Genetic Testing.	International
59. Eurordis	2004	Guidelines for organisations providing information on rare diseases	International
60. Human Genetics Society of Australia	2005	Presymptomatic and predictive testing for genetic disorders	Australia

### **Guidelines and position papers about genetic testing: testing in minors**

<b>Guideline developer</b>	<b>Year</b>	<b>Title</b>	<b>Country</b>
61. American Society of Human Genetics: social issues committee	1991	Report on genetics and adoption: points to consider	USA
62. Clinical Genetics Society	1994	The genetic testing of children	UK
63. American Medical Association	1995	Testing children for genetic status	USA
64. American Society of Human Genetics Boards of Directors and The American College of Medical Genetics Board of Directors	1995	Points to consider: ethical, legal, and psychosocial implications of genetic testing in children and adolescents	USA
65. Genetic Interest Group	1995	GIG response to the UK Clinical Genetics Society Report 'The genetic testing of children'	UK
66. German Society of Human Genetics	1995	Statement on genetic diagnosis in children and adolescents	Germany
67. American Society of Human Genetics and the American College of Medical Genetics	2000	Genetic testing in adoption	USA

68. Canadian College of Medical Geneticists	2000	Position statement - Genetic testing of children	Canada
69. American Academy of Pediatrics	2001	Ethical issues with genetic testing in pediatrics	USA
70. Guidelines for genetic testing of healthy children	2003	Guidelines for genetic testing of healthy children	Canada
71. Human Genetics Society of Australia	2005	Predictive testing in children and adolescents	Australia

## Reports about genetic testing

<b>Guideline developer</b>	<b>Year</b>	<b>Title</b>	<b>Country</b>
72. National Academy of Sciences	1975	Genetic screening: programs, principles, and research	USA
73. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research	1983	Screening and counseling for genetic conditions. A report on the ethical, social, and legal implications of genetic screening	USA
74. Health Council of the Netherlands	1989	Heredity: science and society	The Netherlands
75. Royal college of physicians	1989	Prenatal diagnosis and genetic screening. Community and service implications. Summary and recommendations of a report of the Royal College of Physicians	UK
76. Office of Technology Assessment	1990	Genetic counseling and cystic fibrosis carrier screening: results of a survey	USA
77. American Council of Life Insurance / Health Insurance Association of America	1991	Report of the ACLI-HIAA Task Force on Genetic Testing	USA
78. Council for International Organizations of Medical Sciences	1991	Genetics, Ethics and Human Values: Human Genome Mapping, Genetic Screening and Gene Therapy	International
79. European Commission	1991	Working group on the ethical, social, legal aspects of Human Genome Analysis	Europe
80. Royal college of physicians	1991	Ethical issues in clinical genetics	UK
81. American Association for the Advancement of Science	1992	The Genome, Ethics and Law: issues in genetic testing	USA
82. Office of Technology Assessment	1992	Cystic fibrosis and DNA tests: implications of carrier screening	USA
83. Science council of Canada	1992	Genetics in health care, Report 42	Canada
84. Danish council on ethics	1993	Genetic screening	Danemark
85. European Parliament	1993	Draft report on the ethical aspects of new biomedical technologies,	Europe

			particularly prenatal diagnosis	
86.	Nuffield Council on Bioethics	1993	Genetic screening: ethical issues	UK
87.	Institute of Medicine	1994	Assessing Genetic Risks	USA
88.	Unesco :International Bioethics Committee	1994	Report on Genetic screening and testing	International
89.	Unesco :International Bioethics Committee	1995	Genetic counselling	International
90.	Council of Europe: working party on human genetics	1997	Steering committee on bioethics	Europe
91.	Advisory Committee on Genetic Testing	1998	Genetic testing for late onset disorders	UK
92.	British Medical Association	1998	Human genetics: choice and responsibility	UK
93.	Nuffield Council on Bioethics	1998	Mental disorders and genetics	UK
94.	Danish council on ethics	1998	Debate Outline on Fetal Diagnostics	Danemark
95.	National health and medical research council	2000	Ethical aspects of human genetic testing: an information paper	Australia
96.	Secretary's Advisory Committee on Genetic Testing	2000	Enhancing the Oversight of Genetic Tests	USA
97.	Unesco :International Bioethics Committee	2000	Report on confidentiality and genetic data	International
98.	WHO	2000	Statement of the WHO Expert consultation on new developments in human genetics	International
99.	Organisation for economic co-operation and development	2000	Genetic testing. Policy issues for the new millennium	International
100.	Danish council on ethics	2001	Genetic investigation of healthy subjects - report on presymptomatic gene diagnosis	Danemark
101.	European Parliament. Temporary Committee on Human Genetics and Other New Technologies in Modern Medicine	2001	Report on the ethical, legal, economic and social implications of human genetics	Europe
102.	Human Genetics Commission	2002	Inside information. Balancing interests in the use of personal genetic data	UK
103.	Nuffield Council on Bioethics	2002	Genetics and human behaviour	UK
104.	WHO	2002	Report of a WHO Meeting on collaboration in medical genetics	International
105.	Australian Law Reform	2003	Essentially yours: protection of human genetic information in Australia.	Australia

	Commission, National Health and Medical Research Council and Australian Health Ethics Committee		Report 96	
106.	Department of Health	2003	Our inheritance, our future	UK
107.	Gezondheidsraad	2003	Toepassing van de genetica in de gezondheidszorg. Gevolgen van de ontwikkelingen voor de huidige wet- en regelgeving	The Netherlands
108.	Joint Committee on Medical Genetics of the Royal College of Physicians, Royal College of Pathologists and British Society for Human Genetics	2003	Draft document for consultation. Consent and confidentiality in genetic practice: guidance on genetic testing and sharing genetic information	UK
109.	European Commission	2004	25 Recommendations on the ethical, legal and social implications of genetic testing	Europe
110.	Joint Working Group of the Human Genetics Commission and the UK National Screening Committee	2005	Profiling the newborn: a prospective gene technology?	UK

### Genetics and reproduction (will be developed)

	<b>Guideline developer</b>	<b>Year</b>	<b>Title</b>	<b>Country</b>
111.	National Consultative Ethics Committee for Health and Life Science	1985	Opinion on problems raised by prenatal and perinatal diagnosis. Report	France
112.	World Medical Association	1987	World Medical Association Statement on In-vitro Fertilization and Embryo Transfer	International
113.	German Society of Human Genetics	1990	Statement on the prenatal diagnosis of sex	Germany
114.	National Consultative Ethics Committee for Health and Life Science	1990	N. 19 Opinion on embryo research aiming to achieve pre-transfer genetic diagnosis for which a moratorium was declared in 1986	France
115.	German Society of Human Genetics	1992	Statement on prenatal paternity testing	Germany
116.	Comitato nazionale per la bioetica	1992	Diagnosi prenatali	Italy

117.	German Society of Human Genetics	1993	Statement on prenatal diagnosis and termination of pregnancy	Germany
118.	Japan Society of Human Genetics	1994	Guidelines for genetic counseling and prenatal diagnosis	Japan
119.	German Society of Human Genetics	1995	Statement on Preimplantation diagnosis	Germany
120.	Group of advisors on the ethical implications of biotechnology to the European Commission	1996	Ethical aspects of prenatal diagnosis	Europe
121.	American Society of Human Genetics: Board of directors	1998	Eugenetics and the misuse of genetic information to restrict reproductive freedom	USA
122.	American Society for Reproductive Medicine	1999	Sex selection and preimplantation genetic diagnosis	USA
123.	Canadian College of Medical Geneticists	1999	Paternity testing statement	Canada
124.	Advisory Committee on genetic testing	2000	Prenatal genetic testing	UK
125.	American Society for Reproductive Medicine	2001	Preconception gender selection for nonmedical reasons	USA
126.	National Consultative Ethics Committee for Health and Life Science	2002	Reflections concerning an extension of preimplantation genetic diagnosis	France
127.	Danish council on ethics	2003	Microinsemination and pre-implantation genetic diagnosis	Danemark
128.	European Society of Human Reproduction and Embryology	2003	Taskforce 5: preimplantation genetic diagnosis	International
129.	FIGO. Committee for the ethical aspects of human reproduction and women's health	2003	Recommendations on ethical issues in obstetrics and gynecology	UK
130.	German National Ethics Council	2003	Genetic diagnosis before and during pregnancy	Germany
131.	Gezondheidsraad	2003	Handelingen met geslachtscellen en embryo's	The Netherlands
132.	National Consultative Ethics Committee for Health and Life Science	2003	Opinion n. 83 Generalised prenatal screening for cystic fibrosis	France
133.	Unesco: International Bioethics Committee	2003	Report of the IBC on pre-implantation genetic diagnosis and germ-line intervention	International

134.	Human Genetics Commission	2004	Choosing the future: genetics and reproductive decision making	UK
135.	Swedish National Council on Medical Ethics	2004	Statement of opinion on pre-implantation genetic diagnosis	Sweden
136.	Joint HGSA/RANZCOG Prenatal diagnosis and screening committee	2004	Statement	Australia
137.	Council of Europe	2005	Additional protocol to the convention on human rights and biomedicine concerning biomedical research	Europe
138.	European Society of Human Genetics and European Society of Human Reproduction and Embryology	2005	The interface between medically assisted reproduction and genetics: technical, social, ethical and legal issues	International
139.	European Society of Human Reproduction and Embryology	2005	Taskforce 9: the application of preimplantation genetic diagnosis for human leulocyte antigen typing of embryos	International
140.	Human Fertilisation and Embryology Authority	2005	Sex selection: options for regulation	UK

### Genetics and insurance (will be developed)

Guideline developer	Year	Title	Country
141. American Council of Life Insurance	s.d.	Report of the ACLI Subcommittee on Privacy Legislation to the Task Force on Genetic Testing - Genetic Test information and insurance: confidentiality concerns and recommendations	USA
142. Office of Technology Assessment	1992	Genetic tests and health insurance: results of a survey	USA
143. National Institute of Health: NIH-DOE Working group on ethical legal and social implications of Human Genome Research	1993	Genetic information and health insurance report of the Task Force on genetic information and insurance	USA
144. American Society of Human Genetics: ad hoc committee on genetic testing/insurance issues	1995	Genetic testing and insurance	USA
145. British Society of Human Genetics	1998	Statement on Genetics and Life Insurance	UK
146. Human Genetics Society of	1999	Predictive genetic testing and insurance	Australia

	Australia			
147.	European Society of Human Genetics	2000	Genetic information and testing in insurance and employment: technical, social and ethical issues	Europe
148.	Human Genetics Commission	2001	The use of genetic information in insurance: interim recommendations of the human genetics commission	UK
149.	hm Government and Association of British Insurers	2005	Concordat and moratorium on genetics and insurance	UK

### Genetics and workplace (will be developed)

Guideline developer	Year	Title	Country
150. Office of Technology Assessment	1992	Genetic monitoring and screening in the workplace	USA
151. Danish council on ethics	1993	Genetic testing in appointments etc	Danemark
152. National Consultative Committee for Bioethics	2002	Advies nr. 20 van 18 november 2002 betreffende predictieve genetische tests en HIV-tests in het kader van arbeidsverhoudingen	Belgium
153. European Group on Ethics in Science and New Technologies to the European Commission	2003	Ethical aspects of genetic testing in the workplace	Europe
154. GeneWatch UK	2003	Genetic testing in the workplace	UK

### Genetics and biobanking (will be developed)

Guideline developer	Year	Title	Country
155. National Consultative Ethics Committee for Health and Life Science	1991	N. 25 Opinion regarding the application of genetic testing to individual studies, family studies, and population studies (problem related to DNA banks, cell banks and computerisation)	France
156. National health and medical research council	1999	Guidelines for genetic registers and associated genetic material	Australia
157. Human Genetics Commission	2000	Whose hands on your genes. A discussion document on the storage protection and use of personal genetic information	UK

### Genetics and direct testing (will be developed)

<b>Guideline developer</b>	<b>Year</b>	<b>Title</b>	<b>Country</b>
158. Human Genetics Commission	2003	Genes direct. Ensuring the effective oversight of genetic tests supplied directly to the public	UK
159. National Consultative Committee for Bioethics	2004	Advies nr. 32 van 5 juli 2004 betreffende de vrije beschikbaarheid van genetische tests	Belgium
160. National Consultative Ethics Committee for Health and Life Science	2004	Avis n. 86 Problèmes posés par la commercialisation d'autotests permettant le dépistage de l'infection VIH et le diagnostic de maladies génétiques	France

### **Genetics and patenting (will be developed)**

<b>Guideline developer</b>	<b>Year</b>	<b>Title</b>	<b>Country</b>
161. British Society of Human Genetics	1997	Patenting of Human Gene Sequences and the EU Draft Directive	UK
162. German Society of Human Genetics	1997	Statement on the Patenting of human genes and DNA-sequences	Germany
163. British Society of Human Genetics	1998	Patenting and clinical genetics	UK
164. American College of Medical Genetics	1999	Position statement on gene patents and accessibility of gene testing	USA
165. Organisation for economic co-operation and development	2002	Genetic inventions, intellectual property. Rights and licensing practices. Evidence and policies	International
166. Canadian College of Medical Geneticists	2002	Patenting of the Human Genome	Canada
167. WHO	2005	Genetics, genomics and the patenting of DNA	International