FIFTH SESSION OF THE
INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)
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FOLLOW-UP OF THE IMPLEMENTATION OF
THE UNIVERSAL DECLARATION ON
THE HUMAN GENOME AND HUMAN RIGHTS
I. **INTRODUCTION**

1. In 1993, the Director-General of UNESCO created the International Bioethics Committee of UNESCO (IBC) to encourage the debate, at a world-wide level, on the ethical, social and human consequences of the rapid development of the life sciences. At its 27th session, by Resolution 27 C/5.15 (15 November 1993), the General Conference of UNESCO approved the establishment of the IBC. The IBC, the only international consultative body in the field of bioethics, gathered together approximately 50 well-known people from all regions of the world acting in their personal capacity. The transdisciplinary composition of the IBC enables it to deal with the diversity of issues that advances in research and their application in the field of the life sciences give rise to.

2. By the same resolution, the General Conference of UNESCO invited the Director-General:

   "to continue in 1994-1995 the preparation of an international instrument on the protection of the human genome and to report to it at its twenty-eighth session on the implementation of this resolution".

3. The Director-General therefore gave the IBC a task of primary importance - to make an exploratory study of the conditions for the drafting of an international instrument for the protection of the human genome. The Legal Commission, established within the IBC, was entrusted with the task of making suitable proposals on the form and content of the possible international instrument. The first draft, examined by the IBC at its second session resulted in the drafting of an Outline of a declaration (7 March 1995) based on universally recognized rights and freedoms.

4. On the basis of the Director-General’s Report, the General Conference, at its 28th session, invited the Director-General by Resolution 28 C/2.2 to:

   "draw up a preliminary draft declaration along these lines, which he should communicate to the Member States for their comments, and to convene, in 1997, a committee of governmental experts (category II) to be entrusted with the finalization of this draft declaration, with a view to its adoption by the General Conference at its twenty-ninth session (...)"

   (paragraph 2).

5. To carry out this resolution and taking into account Decision 150 EX/8.3 of the Executive Board taken during its 150th session (14-31 October 1996), the Director-General invited the Member States to be represented in a meeting of the Committee of Governmental Experts for the drawing up of a declaration on the subject, which was held at the Organization’s Headquarters from 22 to 25 July 1997. On the basis of the work of the International Bioethics Committee of UNESCO (IBC) carried out between 1993 and 1997, the Committee of Governmental Experts drew up and adopted, by consensus, the text of the “Draft of a Universal Declaration on the Human Genome and Human Rights”, which was presented to the General Conference at its 29th session.

6. At its 29th session, when adopting, unanimously and by acclamation, the **Universal Declaration on the Human Genome and Human Rights** (Resolution 29 C/16), the General Conference also adopted Resolution 29 C/17 entitled **"Implementation of the Universal Declaration on the Human Genome and Human Rights"** that laid the foundation for the modalities of the follow-up of the implementation of the Declaration.
7. The *Universal Declaration on the Human Genome and Human Rights* aims at ensuring the development of human genetics on lines which will fully respect the dignity and human rights of the individual, and be of benefit to humanity as a whole. The progress of research in human genetics, which holds great promise for the health and welfare of humanity, might also be used for harmful purposes contrary to human dignity, human rights, or respect for the integrity of the human race. It is incumbent on the international community to guard humanity against such risks by proclaiming the principles whose universal observance will forestall any departure from them.

8. The Declaration recalls three essential principles which are fundamental to the protection of humanity as regards the implications of biology and genetics: human dignity, freedom of research and human solidarity.

9. It also reaffirms the need for a democratic debate on the progress of genetics so as to enable society to fulfil its responsibilities. From this point of view, it stresses the importance of international co-operation in furthering the dissemination of knowledge, and the advantages of promoting bioethics teaching.

10. As a guide to its implementation, the Declaration stipulates in *Section G*, entitled "Implementation of the Declaration", that in subscribing to the principles set forth in the Declaration: "(...) States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation". It is therefore incumbent on states to identify the most appropriate measures for the promotion of these principles, whether through the setting of standards or the provision of incentives. By adopting the Declaration, states give solemn recognition to the importance of these principles with respect to the need to promote and protect human rights. In addition, the terms of the Declaration assign to the IBC, *inter alia*, the delicate task to "(...) make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration".

II. WAYS IN WHICH UNESCO'S STANDARD-SETTING INSTRUMENTS ARE MONITORED

11. It is interesting to recall here that no declaration adopted by the Member States of UNESCO has yet led to the establishment of a monitoring mechanism. One particular case, however, needs mentioning - that of the *Declaration on Race and Racial Prejudice*, adopted by the General Conference on 27 November 1978. When adopting this Declaration, the General Conference, in 20 C/Resolution 3/1.1/3, also invited the Director-General to prepare a comprehensive report on the world situation in the fields covered by the Declaration on the basis of information supplied by Member States. In the same Resolution the General Conference also invited the Director-General to submit to it any comments and recommendations deemed necessary to promote the implementation of the Declaration.

12. In general, the procedures for monitoring UNESCO standard-setting instruments or instruments drawn up under its aegis aim to:

(i) inform States on the way in which the instruments are applied;

(ii) encourage States to apply these instruments;

(iii) ensure that they are correctly applied;
13. These procedures are defined:

(i) in the **Constitution** adopted by the General Conference at its fifth session (1950) (Articles IV, paragraph 4, and VIII);

(ii) in the **Rules regarding recommendations to Member States and international conventions** laid down by Article IV, paragraph 4, of the **Constitution**, which sets out the procedure for presenting and considering reports from Member States under Articles IV and VIII of the **Constitution**;

(iii) in **UNESCO's standard-setting instruments**, some of which make provision for special mechanisms (conventions for the protection of cultural heritage, 1954 and 1972, regional conventions on the recognition of higher education studies, diplomas and degrees, etc.).

(iv) in **Resolution 15 C/12.2**, adopted by the General Conference at its 15th Session, concerning the procedure enabling the application of standard-setting instruments to be monitored, and the resolutions adopted by the General Conference concerning the implementation of certain specific instruments.

14. The mechanisms for monitoring UNESCO instruments are of three kinds:

(i) mechanisms for which provision is made in the Constitution;

(ii) implementation mechanisms for which provision is made in conventions;

(iii) implementation mechanisms for which provision is made in specific General Conference resolutions.

III. **FOLLOW-UP OF THE IMPLEMENTATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS**

15. The follow up of the implementation of the **Universal Declaration on the Human Genome and Human Rights** comes under the last category mentioned above. According to **Resolution 29 C/17**:

"The General Conference,

(...)"

1. **Urges Member States**:

(a) in the light of the provisions of the **Universal Declaration on the Human Genome and Human Rights**, to take appropriate steps, including where necessary the introduction of legislation or regulations, to promote the principles set forth in the Declaration, and to promote their implementation;

(b) to keep the Director-General regularly informed of all measures they have taken to implement the principles set forth in the Declaration;"
2. **Invites the Director-General:**

(…)

(c) to prepare for the General Conference a global report on the situation world-wide in the fields relevant to the Declaration, on the basis of information supplied by the Member States and of other demonstrably trustworthy information gathered by whatever methods he may deem appropriate;

(…)

(e) to submit his global report to the General Conference, together with whatever general observations and recommendations may be deemed necessary in order to promote the implementation of the Declaration.

16. The follow up of the implementation of the **Universal Declaration on the Human Genome and Human Rights** is at two levels.

**A. AT THE INTERNATIONAL LEVEL**

17. As indicated above, Article 24 of the Declaration deals with the procedure for its follow-up and stipulates that:

"The International Bioethics Committee of UNESCO should contribute to the dissemination of the principles set out in this Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question. It should organize appropriate consultations with parties concerned, such as vulnerable groups. It should make recommendations, in accordance with UNESCO’s statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular regarding the identification of practices that could be contrary to human dignity, such as germ-line interventions."

18. In this regard, it is for the IBC to play a role in following-up the implementation of the Declaration. With this objective, the functions of the IBC are clearly laid down in Article 2 of its Statutes adopted, on 7 May 1998, by the Executive Board at its 154th session, which read as follows:

"1. The Committee shall have the following functions:

(a) it shall promote reflection on the ethical and legal issues raised by research in the life sciences and their applications, as well as encourage the exchange of ideas and information, particularly through education;

(b) it shall encourage action to heighten awareness among the general public, specialized groups and public and private decision-makers involved in bioethics;

(c) it shall co-operate with the international governmental and non-governmental organizations concerned by the issues raised in the field of bioethics as well as with the national and regional bioethics committees and similar bodies;"
in accordance with Article 24 of the Universal Declaration on the Human Genome and Human Rights, hereafter referred to as 'the Declaration':

(i) it shall contribute to the dissemination of the principles set out in the Declaration and to the further examination of issues raised by their applications and by the evolution of the technologies in question;

(ii) it shall organize appropriate consultations with parties concerned, such as vulnerable groups;

(iii) it shall make recommendations, in accordance with UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of the Declaration, and it shall identify practices that could be contrary to human dignity. (...) .

19. In addition, Article 11 of the Statutes of the IBC establishes an Intergovernmental Committee. In the terms of this article:

"1. An Intergovernmental Committee, hereafter referred to as 'the Intergovernmental Committee', is hereby established within the United Nations Educational, Scientific and Cultural Organization (UNESCO).

2. The Intergovernmental Committee shall examine the advice and recommendations of the IBC, including those concerned with the follow-up of the Universal Declaration. The Intergovernmental Committee shall inform the IBC of its opinions. It shall submit its opinions to the Director-General for transmission, together with the advice and recommendations of the IBC, to the Member States, the Executive Board and the General Conference. It may transmit any proposals for the follow-up of the advice and recommendations of the IBC.

3. The Intergovernmental Committee shall be composed of 36 representatives of the Member States elected by the General Conference. Associate Members of UNESCO shall be invited to participate. When electing the members of the Intergovernmental Committee, the General Conference shall take into account cultural diversity, balanced geographical representation and the need to ensure appropriate rotation. (...).

7. Where the Intergovernmental Committee or the Director-General so decides, a Joint Session of the IBC and the Intergovernmental Committee, hereafter referred to as 'the Joint Session', shall be convened. The Joint Session shall foster dialogue between the IBC and the Intergovernmental Committee on matters of mutual concern. Without limiting the generality of such matters, they may include consideration of any proposals to:

(a) amend the Universal Declaration on the Human Genome and Human Rights; or

(b) adopt any further declaration or any other international instrument within the field of competence of the IBC. (...) ."
20. At its 155th session, on 19 October 1998, the Executive Board of UNESCO elected the following 36 Member States as members of the Intergovernmental Committee:

Australia, Bangladesh, Belarus, Benin, Cameroon, Canada, Chile, Congo, Côte d'Ivoire, Cuba, Dominican Republic, Egypt, Finland, France, Gabon, Germany, Ghana, Hungary, India, Indonesia, Iran (Islamic Republic of), Italy, Japan, Lebanon, Lithuania, Morocco, Mexico, Netherlands, Nigeria, Peru, Republic of Korea, Russian Federation, South Africa, Tunisia, United Kingdom and Venezuela.

The Intergovernmental Committee will be renewed at the 30th session of the General Conference (October-November 1999).

21. In addition, the implementation of the Declaration will be followed up regularly by the community of Member States of UNESCO. Indeed, in accordance with the Statutes of the IBC, the Director-General is invited to present an overall report on the implementation of the Declaration at the General Conference of UNESCO.

B. AT THE NATIONAL LEVEL

22. At its 28th session, in November 1995, the General Conference stressed the importance of ethics committees by adopting Resolution 28 C/2.2 which invited “the Director-General to provide assistance to those States which may request it for the creation of national bioethics committees to be concerned with the protection of universally recognized rights and freedoms”.

23. The Universal Declaration on the Human Genome and Human Rights, foresees the creation of bodies for study and counsel which are capable of promoting the principles laid out in the Declaration. Article 16 of the Universal Declaration stipulates that: "States should recognize the value of promoting, at various levels, as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications”.

24. Furthermore, in Article 23, in the context of the promotion of the principles set out in the Declaration, special emphasis is put on the need to “encourage exchanges and networks among independent ethics committees, (...) to foster full collaboration”.

25. To give effect to the principles set out, and in addition to possible standard-setting action, the Universal Declaration on the Human Genome and Human Rights stresses the importance of undertaking measures which would heighten the awareness of individuals that life sciences do not in themselves guarantee social and human progress, though they are called on to contribute to it, and that this is a matter to be ensured by States.

26. Apart from the setting up of national bioethics committees, the implementation of the Declaration should be accompanied by actions for training and information. Under the terms of Articles 20 and 23 of the Declaration, States undertake to promote, inter alia, education in bioethics and research associated with it, and encourage training in interdisciplinary fields. In addition to the professionals concerned (for example biologists, doctors and jurists), education in bioethics is intended for each one of us and its purpose is to make bioethics an intrinsic component of general knowledge of the future. Bioethics, as a multidisciplinary approach to the relations between man and the life sciences, should include the necessary scientific and technological bases to make it possible to raise fundamental questions and promote an ethic of freedom and responsibility. Teaching should therefore be developed at all appropriate levels according to specific features of national education systems.
27. The choices that advances in biology and genetics call for necessarily relate to a concept of the individual and his or her rights and duties. Far from being a matter for experts, they involve genuine choices of society in which all members of the community should be involved. In addition to bioethics teaching, States should support all research, information or training activities which can foster public debate on these issues. For example, it would be useful to encourage nationally, theses, conferences and publications on bioethics.

IV. UNESCO'S ACTION

28. The adoption of the *Universal Declaration on the Human Genome and Human Rights*, a moral commitment by States, is a starting point and not an end in itself. If the Declaration encourages the Member States of UNESCO to take steps that can put the Declaration into practice and thus ensure its continued existence, it entrusts to UNESCO the tasks that have been set out to support the action by States, as stipulated, in particular, in Article 19, paragraph b) of the Declaration or in paragraph 2 of Resolution 29 C/17 UNESCO's action appears in various fields.

A. DISSEMINATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

29. Upon adoption, the Declaration and the Resolution 29 C/17 for the “Implementation of the Universal Declaration on the Human Genome and Human Rights” were widely distributed. On 11 November 1997, the Director-General addressed them to the Secretary-General of the United Nations, Executive Heads of Specialized Agencies of the United Nations system, the United Nations High Commissioner for Human Rights, the United Nations High Commissioner for Refugees, the Rector of the United Nations University, members of the International Committee of Bioethics (IBC), thanking the latter for their valuable contribution to the drafting of the Declaration, and to all the Permanent Delegations. The Declaration and the Resolution for the implementation were also sent to intergovernmental and non-governmental organizations concerned.

30. In addition, the *Universal Declaration on the Human Genome and Human Rights*, accompanied by the Resolution for its implementation and preceded by a preface signed by the Director-General, was published as a brochure in the six working languages of the General Conference. More than 60,000 copies were sent to Permanent Delegations, National Commissions, Parliaments, ethics committees and similar institutes, academies and universities, ombudsmen and numerous specialists. The Declaration was also distributed to specialized agencies of the United Nations, numerous intergovernmental and non-governmental organizations, UNESCO offices, Associated Schools and UNESCO Associations, Centres and Clubs. It was also reproduced in specialized reviews such as: “The UNESCO Courier”, “Diogène”, the “Dictionnaire permanent de la bioethique” (France), “Derecho y Genoma Humano” (Spain), the Chilean medical review, several Catholic reviews, etc. The Declaration, which has been mentioned in a number of periodicals such as the “International Law Journal”; the “American Medical Association Journal”, etc., has also been translated into Catalan, German and Polish, and the brochure is now also available in Greek and in Italian. The text of the Declaration has also been produced as a poster - in English, French and Spanish - and has been widely distributed.
B. **Promotion of the Principles of the Declaration through Education, Training and Information**

31. Again to encourage the dissemination of the principles laid out in the Declaration, various tools have been conceived and thus the text of the Declaration together with the Resolution for its implementation can be found on the Internet site ([http://www.unesco.org/ethics](http://www.unesco.org/ethics)). It should be noted that many of the numerous sites devoted to biology and genetics (universities, centres and specialised institutes, etc.) refer back to the UNESCO site. In the framework of Article 11 of the Declaration, a kit entitled “No to Human Cloning” was prepared in English and in French making a statement on the debate on the problem of human cloning, at both the international and national level. This aid to the dissemination of the principles of the Declaration has been widely distributed, in particular to the Permanent Delegations, the National Commissions for UNESCO and to more than 600 journalists. The first publication in UNESCO’s new Collection Ethics, entitled “Ethics of Life” has been published in English and in French.

32. In the framework of the promotion of the ethical debate, UNESCO has participated or collaborated in a number of national and international events, in particular in Colombia, Ecuador, France, Hungary, India, Italy, and the United Arab Emirates.

33. For the promotion of education and training in bioethics, a UNESCO Chair of Bioethics was created at the Egerton University at Njoro, Kenya. With a view to the creation of similar Chairs negotiations are underway in Madrid (Spain) and in Oran (Algeria). It is of interest to note that in the framework of the UNESCO Chair at the University of Buenos Aires (Argentina) a meeting of bioethics specialists in Latin America took place on 6 and 7 November 1998. Also, still in the field of education, UNESCO’s assistance has been requested for the setting up of a pilot project for teaching bioethics in training schools for secondary-school teachers. Finally, UNESCO participated in teaching and lectures at university level in France, Lebanon and Spain.

C. **National Ethics Committees**

34. Society is now measuring the consequences of these advances which lie midway between hope and fear. The decision-makers, in both the public and the private sectors, are becoming increasingly aware of the potential impact of this new form of power. All over the world, they are realizing that there is a need for ethical reflection to accompany scientific research and foresee its applications. The world of scientific research now considers ethical reflection to be an integral part of the development of this field. Similarly, the consortiums of the pharmaceutical industry recognize the fact that ethics has become an essential factor in their strategies for development, and are readily setting up ethics committees.

35. UNESCO’s experience in this field has led it to emphasize the threefold vocation of national bioethics committees:

   (i) First of all, they must carry out ethical reflection on progress in the life and health sciences, and must take account of the arguments that might be put forward by research workers and practitioners as well as the various demands made by society. This reflection, which goes together with scientific progress, must also look ahead to issues that may arise in the future.
(ii) It is then up to them to fulfill an advisory role. Indeed, ethical reflection leads to the formulation of directive principles drawing inspiration from universally recognized rights and freedoms, and detailed advisory opinions. In this way, bioethics committees will enlighten the legislator and, in general, public and private sector managers in the decision-making process. Furthermore, by defining rules of conduct, they may also guide research workers and practitioners in their actions.

(iii) Finally, national bioethics committees should foster education, training and information in this field for specialist groups as well as for the public at large. They must encourage a broad public debate, with the participation of scientists. Thus they will reinforce the process by which society as a whole as well as its members individually become aware of the responsibilities incumbent on them in the face of issues raised by research in biology, genetics and medicine and their applications. This action is indispensable in order to enable informed participation by all the actors in the choices that society will have to make in these fields.

36. The establishment of bioethics commissions, councils and committees unquestionably marks the rise of ethical reflection which is now at the centre of the social concerns of our age. In general, these bodies are established at four different levels. The following typology could be established:

- **at the local level**: a committee attached for example to a hospital, which is consulted about questions raised in connection with hospital practices;
- **at the institutional level**: an ethics research review board, connected for example to a research funding institution, which is expected to examine research protocols from an ethical point of view;
- **at the professional level**: an ethics committee attached to a professional association expected to examine, for example at the request of the medical association, issues related to medical ethics;
- **at the national level**: an ethics committee or commission, which gives its opinion or formulates recommendations on topics which have been submitted to it by various governmental bodies or by non-governmental organizations.

37. In the framework of the last category, there are several long-established national commissions, councils and committees. UNESCO encouraged the creation of many of them, in particular in Cameroon, Côte d’Ivoire, Cuba, Ecuador, Egypt, Estonia, India, Jordan, Lebanon, Poland and Tunisia, to mention but a few.

38. The structure, organization and functioning of these committees may differ greatly. Some of them were set up by presidential or ministerial order, others by parliamentary decision. At times they were created following national conferences or on the initiative of non-governmental organizations or even private institutions. Sometimes, they come under a medical council or are attached to a para-governmental institution.

39. The characteristic common to all these committees is their consultative nature. They furnish advice and opinions to the institutions that approach them. Their standpoints, even when they are non-governmental committees, have a definite influence on governmental and parliamentary decision-making bodies. Very often, they are empowered to take up and examine issues that they consider likely to raise ethical questions.
40. It is the charters constituting these committees that set their composition and the modalities of their functioning. In most cases, their composition is multidisciplinary, ensuring that they include at least doctors, researchers, jurists and philosophers. Some of them provide for the participation of representatives of different currents of thought, religious beliefs and forms of spiritual sensibility while others have a place for representatives of civil society. The way in which their members are appointed varies to a very great extent. It is related to the composition of the committee which may be mixed (for example with one third of the members being appointed by parliamentary decision, one-third by a Medical Council and one-third by a Bar Association) or it may stipulate statutory consultations. It may be of interest to note that the Division of the Ethics of Science and Technology is presently creating a database of the existing national committees.

41. It is important to recall that several international institutions have declared their support for the creation of bioethics committees. Thus, on UNESCO’s initiative, the 93rd Inter-parliamentary Conference in March 1995, attended by parliamentarians from more than a hundred countries, adopted a resolution asking States to establish national committees in order "to monitor protection and respect for the dignity, freedom, identity and integrity of the individual in biomedical research", if they so wish, in co-operation with UNESCO.

42. Similarly, the Conference of Heads of State and Government of the Organization of African Unity (OAU), at its 32nd ordinary session (Yaoundé, Cameroon, 8-10 July 1996), adopted Resolution AHG/Res. 254 (XXXII) on bioethics, in which it “pledges to set up consultative bodies at both country and inter-African levels to promote the exchange of experience obtained, among such bodies”.

43. The United Nations Human Rights Commission, at its 53rd session in April 1997, adopted Resolution 1997/17 on "Human Rights and Bioethics" inviting "Governments to consider establishing independent, multidisciplinary and pluralist committees of ethics", in co-operation with UNESCO.

44. More recently, the VIIth Iberian-American Summit of Heads of State and Government (at Isla Margarita, Venezuela, 7-9 November 1997) supported the creation of national ethics committees, depending on the context and needs of each country and in co-ordination with UNESCO.

V. INFORMATION COMMUNICATED BY MEMBER STATES RELATIVE TO THE IMPLEMENTATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

45. By circular letter CL/3478 of 13 March 1998, the Director-General transmitted to the Member States of the Organization the text of the Universal Declaration on the Human Genome and Human Rights, together with Resolution 29 C/17 adopted for the implementation of the Declaration. Furthermore, the Director-General drew the attention of Member States in particular to paragraph 1(a) of this Resolution in which the General Conference urges them to take appropriate steps including where necessary the introduction of legislation or regulations, to promote the principles set forth in the Declaration, and to promote their implementation. In his letter, the Director-General invited Member States to inform him, no later than 30 June 1998, of the texts of any legislation or regulations already adopted, or in preparation in the fields of bioethics, in particular genetics and biotechnology.
46. By 15 October 1998, the Secretariat had received contributions from the following 23 Member States:

Austria, Benin, Colombia, Dominican Republic, Egypt, Ecuador, Estonia, Germany, Indonesia, Ireland, Iceland, Italy, Japan, Luxembourg, Mexico, Namibia, New Zealand, Niger, Norway, Poland, Portugal, Slovakia and the United Kingdom.

47. A letter was therefore sent, on 3 November 1998, to States which had not replied to the Director-General’s letter, to remind them that it was important that pertinent information be transmitted to the Secretariat. In fact, the Director-General’s Report to the General Conference will reflect all the information that he will have received.

48. The IBC members will find in the Annex elements of information communicated by Member States as well as other information already at hand in the Secretariat.

VI. CONCLUSION

49. To give effect to the above orientations, in addition to an eventual action at the normative level, the Universal Declaration on the Human Genome and Human Rights underlines the importance of actions for education, training and information. These should help to strengthen individual awareness of the fact that life sciences do not in themselves guarantee social and human progress even if their vocation is to contribute to it.

50. The success of any strategy for the follow-up of the Declaration will depend mainly on the firm commitment by States to implement it and their ability to mobilize the resources needed. With this in view, the International Bioethics Committee of UNESCO, through the intermediary of its members, has a role of paramount importance to play to promote the principles laid out in the Declaration and to assure the pertinence and the effectiveness of any action undertaken to this effect. For example, the members of the IBC could be the relay for action taken by UNESCO in the States of which they are a national, and, if needed, counsel their national authorities on the steps likely to be taken in the framework of the implementation of the Declaration, in particular by way of legislative or regulatory measures taken in the field of bioethics.
ANNEX

FOLLOW UP OF THE IMPLEMENTATION OF THE UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

INTRODUCTION

Of the laws and policies of the States listed below, information has been compiled from the replies by Governments to the letter addressed to Member States by the Director-General of UNESCO in March 1998.

In some instances, recourse was made to secondary sources such as government policy statements in intergovernmental bodies or regional commitments (e.g., United Nations and Council of Europe documents were used where the national texts were unavailable, incomplete or unofficial). Information was also gathered from the World Health Organization’s International Digest of Health Legislation Issues (IDHL) such as informed consent, patients’ rights, discrimination in the labour market and clinical trials have also been included in the search. These issues will be especially relevant to those countries which have no legislation on the human genome per se, but which have addressed similar concerns in a more general manner as part of their health and social laws and would rather protect the human genome and enforce human rights in an implicit manner.

The national laws and policies discussed below give an overview of work done concerning the ethical and legal issues in the field of genetics and gene technology in States whose legal systems may be different but are nevertheless based on the tradition of common or civil law. As wide a spectrum as possible has been taken into account in all geographical regions. It does not purport to be exhaustive and requires regular updating. One method by which developments at the national level could be recorded as they occur would be for Member States of UNESCO to provide regular information on national implementation of the principles of the Universal Declaration on the Human Genome and Human Rights.

The examination of codes of ethics regulating professional conduct of scientists and doctors could also be a useful mechanism. They are often couched in general terms and apply to all types of scientific activities including research on the human genome. Due to the rapidity with which science develops and the time it often takes to formulate it into policy and translate it into legally enforceable regulations at the national level, the Declaration’s most useful purpose is that it lays down the minimum standards to guide States morally in their commitment to respect the dignity of the human being in those countries where there is a legal vacuum on the question.
COLLECTED DATA

ARGENTINA


The preambular paragraphs and sections 1 and 2 of the above-mentioned Decree no. 200 recall that the protection of the dignity of the human person is among those tasks which cannot be delegated by the State. The State must also ensure and guarantee "the appropriate use of the means and techniques used on and applied to human beings". The Preamble to this Decree also recognises the following:

(i) whereas scientific progress of which the public is aware renders possible the realization of human cloning experiments that give rise to the customs and cultural values proper to the people;

(ii) for this reason, it is of the utmost urgency that all the activities associated with cloning experiments, particularly with regard to human beings, be regulated, controlled, and supervised;

(iii) and that the National Government has taken note of the impact generated in the international community as a consequence of scientific progress associated with cloning;

(iv) and that the Government has also taken note of the opinions expressed by representatives of different religious faiths and scientific establishments, as well as the decisions adopted by the governments of various countries determining concrete positions. In this regard it prohibits "all cloning experiments involving human beings" and obligates "the Ministry of Health and Social Action to formulate a draft law in this respect within a maximum period of sixty days.

AUSTRALIA

A report on the *Ethical Aspects of Research on Human Gene Therapy*, was issued by the National Health and Medical Research Council (NHMRC) in 1987. This report includes background material on the DNA treatment of patients with inherited diseases (the grounds for gene therapy, DNA treatment of somatic cells, recombinant DNA technology, etc.). It also contains, *inter alia*, the terms of reference of the medical research ethics committee and the NHMRC's statement on human experimentation.

The *Guidelines for the Use of Genetic Registers in Medical Research*, were issued by the National Health and Medical Research Council in 1991. These guidelines deal with the use of registers in clinical practice (conventions of current use) and the use of genetic registers in medical research (the responsibilities of the keepers of registers and the Institutional Ethics Committee).

AUSTRIA

The purpose of the Gene Technology Law is to protect the health of persons and their progeny from damage resulting from interventions involving the human genome, genetic testing or the effects of genetically modified organisms and to protect the environment.

Somatic gene therapy in humans may be carried out only in keeping with the current state of science and technology and for the purposes of therapy, the prevention of serious diseases in humans or in order to establish appropriate procedures within the framework of a clinical trial (section 76). Moreover, such therapy can only be carried out if it can be established that it is in accordance with the current state of science and technology and that such therapy will not give rise to any modification of the genetic material of the germline.

If, in accordance with the current state of science and technology, the risk of modification of the genetic material cannot be entirely excluded, somatic gene therapy should be used only if the risk entailed is outweighed by the anticipated benefits for the person concerned. Such therapy should only be used on persons who are definitely unable to have descendants.

Cells from the germline of persons who have undergone such treatment should not be used for the production of embryos outside the body of a woman (section 74).

Genetic testing in humans for scientific purposes and for training may be carried out only with the express consent of the person undergoing such testing or in the context of “anonymous” tests, i.e. if “accompanied by a code rather than a name, and if association of this code with the person undergoing the test is only possible in the establishment conducting the test” (Article 66.1).

The person undergoing the test, or his legal guardian, is entitled to comprehensive counselling both before and after a genetic test which has been undertaken to detect a predisposition to a hereditary disease or in order to detect the carrier state of a disease (section 69.1).

Counselling includes a relevant and comprehensive discussion of all test results and medical facts, including their social and psychological consequences; in the case of prenatal genetic testing, counselling should on no account take the form of mandatory instructions. Accordingly, it is appropriate that additional non-medical counselling be provided by a psychotherapist or social worker. Specific references to such counselling possibilities shall be provided in written form (section 69.2).

The Gene Technology Law permits the person undergoing the testing to consult all data concerning him on request, including any unforeseen results of direct clinical significance. This information shall be presented in such a way that, particularly in cases where the person concerned has not requested such communication, it does not have a disturbing effect upon him; in doubtful cases, this information may be completely omitted (Article 71 [1.1 and 2]).

The law also specifically prohibits discrimination by employers and insurers on the grounds of genetic data. Employers and insurers are prohibited from collecting, requesting or accepting the results of genetic testing either from their employees, from persons seeking employment, insured persons or insurance personnel. They are also prohibited from utilizing such data in any way (section 67).

The law ensures the confidentiality of data and obliges establishments to proscribe detailed procedures to ensure that unauthorized persons cannot obtain access to such data (Article 71.5). The results of genetic testing may only be disseminated or published if appropriate measures are taken to ensure that, with limited exceptions, the person undergoing the test cannot be identified (section 66 [2]).
Data on genetic testing may only be communicated to the following people: those undergoing the tests; their legal representatives; the staff of the establishment directly concerned with collecting, processing or evaluating the data; the physicians who arranged for the testing to be carried out; and the attending physician or the physician making the diagnosis (section 71 [4 a-d]).

Another person can only have access if the person undergoing the testing expressly consents in writing. Such consent can later be withdrawn in writing (section 71 [4e]).

In cases where the results of a genetic test necessitates the involvement of the relatives of the person tested or where a serious risk exists that the relatives of the person tested will develop the disease in question, the physician responsible for genetic testing must “recommend to the person undergoing the testing that he advise those members of his family likely to be affected to undergo genetic testing and counselling” (section 70 [1 and 2]).

The law establishes a Commission on Gene Technology under the authority of the Federal Minister for Health, Sport, and Consumer Protection, which regulates its composition and functions as well those of its expert subcommittees. The law also requires the Minister to issue a Gene Technology Code in which the Commission is to record the current state of science and technology regarding work with genetically modified organisms (GMOs), the release of GMOs and the marketing of products containing them, genetic testing and somatic gene therapy in humans (Articles 80-99).

The Minister is empowered to grant authorisation to establishments to conduct genetic testing in humans for medical purposes if they fulfil a number of conditions stipulated by the law. The advice of an appropriate scientific committee is always sought for a request for authorisation (Article 68).

There are certain prerequisites for granting such authorisation, including the establishment’s ability to prove it has the necessary staffing and resources to carry out the genetic testing in accordance with the current state of scientific and technological knowledge and that the resulting data are protected. If these prerequisites are not met, the Minister may withdraw its authorisation. In the event of serious shortcomings, the Minister is empowered to issue appropriate instructions and can ban further genetic testing pending implementation of these instructions (Article 68 [1-4]).

In order to ensure that genetic testing and the associated counselling are conducted in an irreproachable manner, the Federal Minister of Health, Sport and Consumer Protection and the Federal Minister of Science and Research are jointly empowered to issue detailed regulations. The person responsible for the establishment conducting gene tests must submit a report every two years describing the tests carried out (Article 75).

Somatic gene therapy in humans can only be conducted by a physician in a hospital establishment authorised for that purpose (Article 75[1]). Clinical trials for the purposes of somatic gene therapy also require the Minister’s authorisation, that is granted following the advice of an expert scientific committee of the Commission on Gene Technology and on the advice of a Medicaments Board.

In the event that GMO’s are to be used in such a trial, approval will only be granted for trial if the GRO’s are not expected to be subsequently released. This condition is cancelled if prior authorisation has been granted for such release (Article 77).

Belarus

person may be subjected to medical or other experimentation without his consenting (section 25). All persons are equal before the law and are entitled, without any discrimination, to an equal policy with regard to their rights and legitimate interests (section 22). The guarantee of the rights and freedoms of the citizens of the Republic of Belarus is the supreme aim of the State (Article 21). Every person has the right to life and the State guarantees to protect the life of individuals against any illegal affront (section 24). Limitations on individual rights and freedoms may only occur in the cases provided by law, in the interest, inter alia, of the health of the population (section 23). Every person has the right to a favourable environment and to compensation for damage to the environment resulting from a violation of this right (section 46). Individuals have a corresponding duty to protect the natural environment (section 55).

BELGIUM

- Crown Order of 1987 as amended on Standards to be complied with by centres for human genetics

Centres for human genetics undertake analyses in cytogenetics, biochemistry, ultrastructure, nucleic acids, and recombinant DNA and to make use of all other techniques required for the above mentioned diagnostic purposes (section 81; see also IDHL, 1994, vol. 45, no. 2, p. 164).

The law defines “centres for human genetics” as centres in which diagnoses are made on the hereditary nature of both mental and physical malformations and anomalies, the nature of such malformations and anomalies and the determination of whether a person is a carrier of hereditary characteristics thereof. In order to be allowed to operate, these centres require approval by the Minister responsible for Public Health and must meet rigorous standards in terms of human and operational resources.

Centres for human genetics are obliged to organise regular consultations in genetic counselling. These consultations must enable the centre to make a diagnosis, or to do whatever needs to be done in order for a diagnosis to be made. The persons seeking consultation must receive as much necessary information as possible in order to allow them to make an informed judgement (Articles 6-8). The centres are also obliged to compile genetic data for epidemiological purposes, in accordance with the rules and procedures laid down by the Minister responsible for Public Health (Article 10).


This law prohibits the communication of genetic data that may not be communicated to insurers by persons applying for life-insurance contracts (section 5). It also stipulates that the medical examinations necessary for concluding and enforcing an insurance contract must be based on the case history determining the current state of health of the applicant for insurance and not on genetic testing techniques appropriate for determining his future state of health (section 95 [Medical Information] of Chapter I [Joint Provisions] of Title III [Personal Insurance]).

BENIN

The authorities of Benin intend to co-ordinate the launching of an African network of National Bioethics Committees. In replying to the Director-General's letter, the authorities of Benin stated that although no legislation was yet in force in their respective countries, provisions of the Universal Declaration were being debated at national level in each country in order to lay the groundwork for corresponding legislation.
BRAZIL


Law no. 8974 of 5 January 1995, includes definitions of a genetically modified organism (GMO) as one whose genetic material (DNA/RNA) has been modified by a genetic engineering technique and genetic engineering as an activity involving the manipulation of molecules of recombinant DNA/RNA.

Under section 4, the law is not applicable if genetic modification has been carried out through one of the following techniques: mutagenesis; formation and utilization of somatic cells of animal hybridomas; cellular fusion, including protoplastic fusion of plant cells produced through traditional methods of culture; and the auto-cloning of non-pathogenic organisms obtained in a natural manner.

The following activities are prohibited in connection with GMOs: the genetic manipulation of living organisms or the in vitro manipulation of natural or recombinant DNA/RNA, carried out in violation of the rules laid down by this law; the genetic manipulation of human germ cells; in vivo interventions on human genetic material, except for the treatment of genetic defects, with due respect for the principles of ethics, autonomy, and beneficence and subject to the prior authorisation of the National Technical Commission on Biosafety (CTN Bio); the production, storage, or manipulation of human embryos intended to serve as disposable biological material; in vivo interventions on animal genetic material, except in specified cases; and the release or disposal into the environment of GMOs in violation of the rules established by the CTN Bio and the regulations made for the implementation of this law.

An Internal Biosafety Commission is responsible for, inter alia, providing information to workers likely to be exposed to risks by virtue of the work to which they are assigned on any question relating to health and safety and on the measures to be taken in the event of an accident; establishing programmes of prevention and inspection to assure the proper operation of instalments, and keeping records of the monitoring of each project involving GMOs (section 10).

BURKINA FASO

- Law no 23/94 ADP of 19 May 1994, promulgating the Public Health Code, Book I, General Provisions (sections 1-7) (IDHL, 1995, vol. 46 (4), pp. 451-454), defines the rights and duties inherent in the protection and promotion of public health of the population. Title I defines Health Protection and Promotion as including “the promotion of the health of the individual, the family, and the community by improving living and working conditions through [...] the promotion and development of biomedical research and health services research” (Title I, para. 3).

- Book II, entitled General Protection and Promotion of Public Health, affords general health protection to consumers and workers exposed to risks of infection (sections 112-122, pp.98-101).

- Book IV, entitled Pharmaceutical Products and Other Products and the Traditional Pharmacopoeia, regulates, inter alia, the therapeutic use of human blood, blood plasma and their derivatives (sections 207 325).

There is a general ban on advertising concerning the distribution of blood, blood plasma and their derivatives, with the exception of such substances intended solely for medical information (section 260). For example: “Human blood shall be obtained free of charge from voluntary donors” (section 257 [1]) or “Blood obtained
free of charge from voluntary donors shall, under no circumstances, be the subject of commercial transactions. Private establishments may, however, obtain blood supplies provided that they reimburse the cost of the equipment used for its collection" (section 257 [2]).

As a general rule, the law prohibits the removal from a living human being of a non-paired, non-regenerable organ essential for the preservation of life, even for the purposes of transplantation (section 265). The removal of organs or tissues shall be subject to the express written consent of the donor, given without physical or moral coercion in the presence of a notary or two witnesses (section 266).

If a person has not consented to the removal of organs or tissues from his body after his death, the authorisation of his family or associates shall be required (section 267). Consent given by minors or persons suffering from a mental disability shall be null and void. Consent obtained under any form of coercion shall be equally invalid (section 268). Persons deprived of their liberty may not consent to the donation of their organs or tissues for therapeutic purposes unless such removal is for the benefit of the members of their family and carried out under the conditions laid down in section 266 (section 269).

Article 258 states that the proprietors of establishments equipped with blood banks shall be liable, even in the absence of fault, for risks incurred by voluntary donors, and must take out insurance to cover the liability of their establishments. This insurance shall provide guarantees at least equal to those defined by an Order made jointly by a Minister responsible for Health and the Minister responsible for Financial Affairs. Provision is made for the submission to a court of law of any disputes arising from the implementation of Article 258.

The transplantation of organs or tissues into living persons may not be carried out even for therapeutic purposes, unless the results of research have been satisfactory (section 270). Human organs and tissues intended for transplantation may under no circumstances, be exported from the national territory unless an exemption has been granted by the Minister responsible for Health (section 271).

CANADA (at the Federal level)

The National Biotechnology Advisory Committee (NBAC) issued its sixth report on biotechnology in 1998. It focuses on the following issues for the future development of Canadian biotechnology: leadership, commercialization, science and innovation; market access, intellectual property rights and regulation; the socio-ethical context; and the renewal of the advisory body.

In so far as intellectual property rights and regulation are concerned, the report refers, inter alia, to the necessity to pay particular attention to the composition, mandate and breadth of consultation of the International Bioethics Committee and to the research and commercialization aspects, alongside the environmental, human rights and socio-ethical issues (NBAC Sixth Annual Report, p. 50).

The report makes several recommendations to revise the current biotechnology structure in Canada. It recommends that the Intellectual Property Office should introduce an effective opposition procedure with a time limit period of six months after a patent has been issued. It also recommends that the NBAC should evolve into a new advisory body with a public role and a broader membership and mandate, including a socio-ethical framework for biotechnology policy. It is further recommended that the NBAC raises awareness of issues related to biotechnology and that the body report to the Minister of Industry as a focal point in Cabinet for biotechnology issues.
CANADA (at the Provincial level)

CANADA, ONTARIO

- Ontario Regulation 19/95, formulated under the Consent to Treatment Act (1992), dated 19 January 1995 ("The Ontario Gazette", 4 February 1995, vol. 128, no. 5, pp. 257-258). This regulation provides detailed conditions to determine the capacity of a person to undergo treatment and it guides the health practitioner in assessing the criteria to be used (sections 4 and 5).

- Ontario Regulation 746/94 formulated under the Chiropody Act (1991) of 7 November 1994 ("The Ontario Gazette", 17 December 1994, vol. 127, no. 51, pp. 4605-4607). This regulation provides, inter alia, for the correct keeping of patients' records (Part III, sections 13-15) and for the conditions and circumstances under which information concerning patients can be divulged (section 18). It is an act of professional misconduct for a member of the profession to fail to provide access to or copies from a patient’s health record either to the patient, his legal representative or the persons authorised to act on the patient’s behalf in case of the patient’s incapacity to grant authorisation (section 18 [4]).

CANADA, NEW BRUNSWICK


- Regulation no 92-84 formulated under the Hospital Act, details the keeping of correct medical records of patients (Article 20[1]) and permits the following exceptions to the confidentiality rule of medical records:
  
  (i) upon the written request of a chief executive officer of another hospital when required for care, diagnosis or treatment of the patient;
  
  (ii) upon the request of the patient’s doctor;
  
  (iii) to any person on the patient’s written request or that of his legal representative;
  
  (iv) for approved scientific research or teaching purposes in the hospital, upon a court order;
  
  (v) upon the direction of the Minister or a written request of a person designated by the Minister;
  
  (vi) upon a written request of a representative of the Workers Compensation Board; or
  
  (vii) upon the request of the Department of National Defence or Veteran Affairs regarding members of the Armed Forces (Article 20 and 21[1]).

CHINA

The Law of the People’s Republic of China on the Protection of Maternal and Child Health of 1994 (IDHL, 1995, vol. 461, pp. 39-42) lays down provisions to protect health before marriage and also during pregnancy and childbirth. Medical and health care establishments are authorised to conduct diagnostic procedures regarding genetic diseases in compliance with the requirements laid down by the Administrative Department responsible for the State Council and with their authorisation (section 32). The provisions concerning diagnosis and prevention of genetic diseases are linked to the provisions of contract marriage. [No specific legislation on the human genome was identified].
COLOMBIA

The Ministry of Foreign Affairs of Colombia provided a summary of the Government’s policy.

- **Resolution 8430 of 1993** lays down the norms to be applied in human and animal research, including norms concerning minors, disabled persons and research on cadavers and organs.

- **Resolution 3823 of 1997** creates a Council on Science and Technology responsible to the Minister of Health which sets out norms for the scientific activities in the health sector. **Article 5** of this Resolution regulates use of genetics and biotechnology in humans.

In addition, an awareness campaign on the existing scientific norms applicable has been launched with the participation of the Department for Science and Technology and of Health in partnership with universities and institutions involved in health research. In order to promote the Universal Declaration on the Human Genome and Human Rights, the multilateral directorate of the Ministry of Foreign Affairs has also organised several scientific symposia aimed at adopting appropriate legislation and regulations on the same subject.

**Title II of Law no. 8430 of 1993**, entitled “Research involving Human Beings”, and in particular **Chapter I**, lays down the overall policy regarding research conducted on or involving human subjects. All research involving human beings must be guided by the overriding principle of respect for human dignity and the protection of rights and well-being (**Article 5 of law no. 8430**).

All research undertaken on humans must be justified by scientific and ethical principles; be based on experiments already conducted on animals in laboratories and in other scientific institutions, and only carried out if the expected results cannot be obtained in any other way.

The safety of the beneficiaries is a prevailing consideration; they should be informed of all risks, however minimal, and should under no circumstances contradict **Article 11**, which distinguishes between three categories of scientific activities: those without risk, those with minimal risk and those involving a major risk.

Research cannot be undertaken without the express consent of the persons subjected to the research or their legal representative, except in those cases where the law permits that written consent can be waived and in this case the research must be conducted by competent professionals and supervised by a health institution with the necessary human and material resources to guarantee the well-being of the persons participating in the research. Projects must be approved by the ethics committee of the institution undertaking the research.

The law also ensures that the subject is informed in as simple and non-technical terms as possible of the procedures he will be undergoing and their expected results (**Article 15**). In order for consent to qualify as informed consent, it must be undertaken in writing by the person to undergo the research, or by his legal representative in full awareness of the respective benefits and risks of the research (**Article 15**).

Furthermore, the research project must be elaborated by the head of the research institution in accordance with **Article 15** to qualify as informed consent by the subjects of the research and be approved by the institution’s ethics committee. Information on the type and quantity of the tests to be undertaken as well as their relation to the subjects of the tests should also be provided (**Article 16, paras. a - c**).

Consent to undertake the tests must be given in writing by the subject himself or by his legal representative and, if the subject is unable to write, by a person of his choice who can sign on his behalf (**Article 16. para. d**).
The provision of written consent given by the subject can be waived where the risk to the subject is minimal and where the waiver is authorised and justified by the ethics committee (Title I, para. 1). The law also ensures that where any kind of dependence or subordination exists between the subject of the research and the researcher which impedes the granting of free consent to experiments, such consent may be obtained from another member of the research team which ensures complete independence between the researcher and the subject participating in the research (ibid., para. 2). In cases where it is necessary to determine whether a person has the mental capacity to consent to his/her participation in human experiments, a neurologist, psychiatrist or psychologist must determine the subject's capacity according to the criteria approved by the ethics committee of the institution conducting the investigation (ibid., para. 3). Where the mental faculties of a subject change during the period of experimentation, the advice of a professional - neurologist, psychiatrist or psychologist - of recognised scientific and moral standards must be sought, as well as that of an independent observer who has no relation with the research being undertaken in order to ensure that the subject's capacity, or that of his legal representative, remains intact during the conducting of the research (ibid., para. 4).

In experiments on humans, the privacy of individuals is protected and their identity revealed only when necessitated and with the subjects' authorisation (Article 8).

In case of damage suffered directly by the person participating in the research, the institution undergoing the research must indemnify the subject or his legal representative.

DENMARK


This law also ensures that health data originating from genetic examinations, routine examinations or other sources are not used in an unjustifiable manner on the labour market in order to restrict an employee's possibility of obtaining or retaining a post.

Chapter II entitled "Collection of Data", prohibits an employer from requesting an employee “upon recruitment or during the course of employment, to provide medical data for the purpose of ascertaining whether the employee concerned is suffering or has suffered from a disease, or has shown symptoms of a disease, unless the disease concerned is likely to have a major effect on the employee's work capacity with regard to the work in question, without prejudice to sections 3-6 (section 2). A request for and collection of medical data also includes the conduct of any examination necessary in order to obtain the medical data concerned. An employer may suggest the collection of medical data if the conditions of the working environment justify this in the interest of the employee concerned or other employees, e.g. with a view to ascertaining the employee's risk of developing or contracting a disease (section 2, paras. 1 and 4).

In those instances where the law permits the collection of medical data, an employer must first inform the local labour inspectorate before such examinations are carried out, indicating their scope, the methods to be undertaken, the persons being examined and those supervising the examinations. The employer must show that the examinations are necessary to prevent occupational diseases or the improvement of the
conditions of the working environment. When a medical examination is carried out, the employer must communicate to the person conducting the examination all information necessary in order to carry it out; defray the costs concerned with the examination; and ensure that the examination is carried out without any loss of income for the employee and, as far as possible, within working hours (section 3, para. 4).

A control procedure permits the Director of the Labour Inspectorate to order against or to discontinue any examinations being carried out (Article 3 para. 5). The Minister of Labour may, after having obtained the opinion of the Council of Experts, permit an employer to obtain data in order to ascertain whether an employee is suffering from a disease, manifests the symptoms of a disease or constitutes a risk of infection provided that this is necessary with regard to, in particular:

(i) the safety or health of the consumer or others;
(ii) the external environment; or
(iii) other aspects of a social nature.

The collection of medical data shall be subject to the condition that the interests considered go beyond the employee’s interests and that it is not possible to proceed in any other manner (section 4). Section 9 of the Law 286 of 24 April 1996 indicates that, prior to an examination to ascertain a disease or risks as specified in the law, the employee must be informed orally and in writing of the following details:

(i) the purpose and nature of the examination;
(ii) the method used, its potential risks, consequences and results;
(iii) the type of data that may be obtained from the examination, including the scale of the risk of future disease; the follow-up to the examination, including the information provided to the employer; and the method of preserving the results of the examination and the extent to which the nature of the examination is likely to have an influence on the person’s expectations in life and his view of himself.

The employer must also ensure that the employee is informed, before undergoing the examination, of the potential consequences if he or she refuses to undergo such an examination. The examination may only be carried out with the written consent of the employee concerned, who shall be allowed a minimum period of two working days in order to do this, counting from the day the employee is informed (see Chapter V, “Informed Consent” at section 9 of Law 286 of 24 April 1996).

Chapter VII of Law 286 of 24 April 1996, entitled “Duty of Confidentiality”, requires physicians, clinics, laboratories, public services, etc. to respect the confidentiality of data collected (section 11).  


An Ethical Council was created in Denmark in 1987 according to Law no. 353 of 3 June 1987 (IDHL, 1988, vol. 39, p. 95). Law no. 499 introduces certain amendments to this law, permitting ethics committees in certain cases to decide that research projects based on registers are not subject to the rules regarding informed consent (section 8).

The Central Scientific Ethics Committee is responsible for submitting an annual report on one or more topics (determined in consultation with the Minister of Research) concerned with the follow-up and control by the committees of authorisations that have been granted (section 9).
Research conducted by means of questionnaires and by means of projects based on registers shall only be notified to a regional committee if the projects concerned contain an important element of biomedical research or constitute part of a project that contains an important element of biomedical research, and if they entail health hazards for the research subjects or in any other way constitute a burden for them" (Article 3).


This law regulates scientific practices involving human gametes, fertilised oocytes and embryos (Chapter I) and prohibits certain types of treatment (Chapter 2) and commercial activities (Chapter 3). It also regulates the instances where biological experimentation can be carried out on fertilised human oocytes and gametes intended for use in fertilisation (Chapter 7). Biomedical experimentation on fertilised human oocytes and gametes intended for use in fertilization may only be carried out in two cases:

i) to improve *in vitro* fertilisation or similar techniques intended to bring about pregnancy; and

ii) to improve techniques for the genetic testing of a fertilised ovocyte with a view to establishing the possible presence of a serious hereditary disease or an important chromosome abnormality (pre-implantation diagnosis) (Article 25[1]).

The removal and fertilisation of an ovocyte in order to carry out experiments other than those referred to in 1 and 2 above is prohibited (Article 25.2). Fertilised human oocytes that have been used in biomedical research, including general research to assure their quality for the purpose of implantation, may not be implanted in a woman’s uterus unless the fertilised oocytes are genetically unchanged (unmodified) and unless, according to a technical appraisal carried out in this connection, the research to which the oocytes have been subjected has not damaged them or impaired their subsequent development (Article 27[1]). A scientific ethics committee analyses all projects prior to their authorisation in order to ensure that they conform to the purposes for which such authorisation is requested.

The Law no. 460 of 10 June 1997 prohibits the sale or any activity which in any other manner may contribute to the sale of fertilised or unfertilised human oocytes (Article 12). It also prohibits the export of unfertilised or fertilised human oocytes that have been removed in Denmark for the purposes of artificial fertilisation or research.

The National Board of Health lays down regulations to be applied in connection with donation, use and storage of human oocytes and sperm (Articles 17[2], 20[2], and 22). Any new therapeutic and diagnostic methods in connection with artificial fertilisation techniques can only be used after they have been approved from the ethical and technical health standpoints by the Minister of Health (Article 21[1]).

Chapter 6 entitled “Information and Consent”, stipulates that the written consent to treatment must be obtained from the woman and her spouse or partner before proceeding with treatment for artificial fertilization. Consent must be based on written and oral information concerning the effects and side-effects of the treatment and the associated risks. In cases where sperm or oocytes are donated, written consent shall also be required from the man or woman making the donation (Article 23). The attending physician must also ensure that information is provided on the consequences in civil law that ensue from the fact that a couple receives donated gametes in connection with treatment for artificial fertilisation (Article 24).
ECUADOR

The Authorities of Ecuador submitted information on the various activities being undertaken on a national level to implement the commitments outlined in the *Universal Declaration of the Human Genome and Human Rights*.

With the assistance of UNESCO and Life Laboratories, the First Ecuadorian Biotechnology meeting took place in 1994 and the second in January 1998 and aimed at formulating national policies for scientific development. The main conclusions are outlined below.

An *Andean International Agreement* will prohibit the patenting of human genes in Venezuela, Colombia, Ecuador, Peru and Bolivia, as well as the patenting of products that can have a negative effect on human health, morale and the environment. Progress in biotechnology must benefit human beings, but at the same time it is necessary to identify the social and cultural consequences of such findings. In so far as the human genome is concerned, human dignity is considered to be the natural limit to science. At the same time, human rights and the liberty to undertake research must also be guaranteed by society (see *ibid., Chapter VII*).

A new intellectual property law is in the process of adoption; it will be the basic instrument for the protection of biological inventions. Inventions, and not findings, can be patented. A patent makes an invention the exclusive property of the inventor and allows him to commercialise the invention. It is the process, the microorganisms - transegenes, monoclonal antibodies - which have been created that can be patented but not the product itself. The Ministry of Industry, Commerce Integration and Fisheries regulates patenting. In order for an invention to be patented an application must be made by a lawyer with a detailed report on the technical proceedings of the research, the products to be patented and their industrial application. The following considerations were outlined by the Ecuadorian Government:

(i) the necessity to follow biosecurity norms in handling genetically modified living organisms; the need for effective control of transboundary movements of genetically modified organisms (an Andean community protocol along these lines is being negotiated amongst the member States);

(ii) the risks for the receiver, the vector and the characteristics of the new organism; the proper human resources to handle such scientific activities; and

(iii) the necessity for the proper legal instruments and regulations when manipulating DNA.

The final declaration of the second National Meeting on Biotechnology in Ecuador (January 1998) targeted the following main lines of action:

(i) to gain better knowledge of the state of biotechnical research nation-wide and to establish some strategic lines of action that can contribute to the formulation of policies of scientific development in the country;

(ii) to co-ordinate the various national research efforts under way and their applications in the various sectors of production, health, productive developments and environmental protection;

(iii) to identify the co-ordination mechanisms necessary to attain higher levels of research and utilization of the country’s available resources;

(iv) to encourage the development of joint activities between the public/private academic sector and the productive sector, in order to strengthen the nation’s capacities in the field of biotechnology, which may be applied in the solution of development problems;
to establish a set of fundamental guidelines for the formulation of more relevant strategies which, from the governmental and private sectors, will encourage the scientific and technological research. It was considered important not to confuse tools on molecular genetics with modern biotechnology, the latter dealing with genetic transformation through the technology of (recombinant) DNA. It was proposed that a competent supervisory commission be created to control research in the field. Science and technology should be given the necessary importance in the Constitution, which is presently being revised. Networking between universities and the institutions undertaking the research should also be a necessary part of the process. A third National Meeting on Biotechnology is scheduled for May/June 1999.

**EGYPT**

The information provided by Egypt stated that the Egyptian Bioethics Committee contributes to studies on ethical codes of practice of genetic engineering and biotechnology and proposes legislation to the Government. It regulates its work within the framework of the social and religious values of Egyptian society. Its supervisory role in regulating national activities involving biotechnology is currently under examination. The Egyptian Bioethics Committee is also reviewing educational curricula. A public awareness campaign has been initiated.

**ESTONIA**

Estonia has no specific law at present on the human genome, biotechnology or bioethics. Certain paragraphs in the draft of the Patients Rights Act concern bioethics. According to the Foreign Ministry, the bill will undergo its second reading in the autumn of 1998. An Estonian Council of Bioethics and an accompanying Statute have been established by the Ministry of Social Affairs, which has a formal policy of following the principles adopted by international organisations such as UNESCO, HUGO and others, pending the elaboration of its own laws and regulations in the area.

The authorities of Estonia indicated their intention to ratify the **1998 Council of Europe Additional Protocol on the Prohibition on Human Cloning** in the near future, thereby making it part of the domestic law.

**FRANCE**

- Law of 1 July 1994, regulating the use of medical data in health research.
- Law of 20 December 1998, on the protection of persons participating in biomedical research.
A National Ethics Commission was created in 1983 to advise the Minister of Health on moral issues arising in biological and medical research with implications on humans, on particular social groups or on society as a whole.

In 1988, a law protecting persons undergoing scientific experiments was promulgated. This law distinguished between research intended for therapeutic purposes and research intended to serve a utilitarian function in society at large.

The five laws promulgated in 1994 are all interconnected. Furthermore, the Law of 25 July and the Laws of 29 July directly concern bioethics. The laws are inspired by the following guiding principles:

(i) the inviolability of the human body (Article 16.1, 16.3, 16.4 of the Civil Code), i.e. the fundamental right of every individual to the respect of his/her body and the prohibition of any treatment, without obtaining the prior informed consent of the subject, excepting certain circumstances defined by the law, which diminishes a person’s integrity in his own interest, in the interest of a third party or in the interest of society;

(ii) any diminution of the overriding principle of human dignity of the person depends on the therapeutic benefits to be obtained and the prior informed consent of the individual undergoing the treatment.

A total prohibition exists on all types of conduct which could lead to eugenic practices and any modification of a person’s genetic characteristics whose purpose is to alter their descendants. This does not impede the possibility of research to eradicate genetic illnesses nor the study of genetic characteristics of a human being for medical or scientific purposes. Articles 16.5, 16.6, 16.7 and 16.8 of the Civil Code prohibit the possibility of the human body, its elements and products to be the subject of a right of ownership, thereby guaranteeing against any form of commercialisation of the human body.

According to Law of 1 July 1994, regulating the use of medical data in health research, the patient’s consent is not necessary where the data is used for certain specified types of research, such as skin research and medical research in its widest sense. Every patient has the following rights. firstly to refuse that his medical data be computerized; and secondly to refuse to be informed of the nature of the information communicated to the database, the purpose for which such data will be used, the physical and moral persons to whom such data are communicated and his right to access, correct and oppose the transfer of such data. The Law assures the anonymity of information concerning individuals: any results of research using the data cannot permit the direct or indirect identification of the individuals involved. A consultative committee evaluates the utility of each project requiring identifiable databases.

The Law 94-630 of 25 July 1994, protecting persons undergoing biomedical research prohibits direct research on a patient in emergency cases unless it is of direct benefit to him. Furthermore, all research on persons who have lost their freedom by judicial or administrative measures as well as hospitalized persons who have not consented to treatment and who have no legal representative can only be conducted if a direct and significant benefit is expected from such research. Furthermore, the law prohibits all types of biomedical research on persons who are brain-dead unless such a person or his lawful representative has previously granted consent. The law also modifies the composition, powers and functions of consultative committees responsible for the protection of individuals participating in biomedical research.

According to the Law no 94-653 of 29 July 1994, concerning respect for the human body, the overriding principles of dignity of the human person, respect for the human being and the inviolability and non-patrimonial nature of the human body are enshrined in this law.
Chapter II of the Civil Code as amended by this law is entitled “Of Respect for the Human Body”. Every person has the right to the respect of his body. The human body is inviolable and its elements and its products cannot be the object of a proprietary right (Article 16[1]). The law empowers a judge to take all necessary measures to prevent any attempt at violation of any of these principles (Article 16[2]). All practices which endanger the integrity of the human race and any eugenic practices aimed at organising the selection of persons are prohibited. Without prejudice against research aimed at the prevention or treatment of genetic diseases, no transformation of genetic characteristics aimed at altering the descendant line of a person is permitted (Article 16[4]) and all contracts concerning procreation or gestation on behalf of another person are null and void (Article 16[5]).

The law also prohibits the granting or receipt of remuneration for research on the body, or parts, elements or products thereof (Article 16[6]). In order to preserve the confidentiality of donors, no information capable of tracing the identity of the donor or the recipient can be made available. However, doctors of both donors and recipients may obtain such information in cases of therapeutic necessity (Article 16[8 and 9]).

A new Title III (“Examination of an Individual’s Genetic Characteristics and the Identification of a Person by their Genetic Prints”) specifies that, as a general rule, recourse to examinations of an individual’s genetic characteristics and the identification of a person by his genetic prints is only possible for medical or scientific research and with the prior consent of the participating subject (Article 16[12]).

The law also provides criminal sanctions for any injury brought against the individual resulting from a study of his genetic characteristics or identification of his genetic characteristics. The law sanctions the act of conducting research without obtaining the prior consent of the individual participating in the research (Articles 145-15 of the Code of Public Health) or the misuse of information gathered in the course of medical or scientific research. Moral persons may be held criminally responsible. The same sanctions are attributed to those persons who seek to obtain information relating to an individual’s genetic identity for reasons that are neither scientific, medical nor legal (for example, investigative measures conducted during a judicial process).

A new chapter of the Code of Public Health “Biomedical Offences” punishes all attempts at eugenic practices tending towards the selection of the individual (Article 511[1]).

Section 2, entitled “Protection of the Human Body”, makes it an offence to attempt to obtain the organs of a person in exchange for payment of any kind (Article 511[2]). This also extends to organs obtained from outside France (Article 511[3]) and samples of human tissues, cells or other products of the human body against payment (Article 511[4]).

Law no. 94-654 of 29 July 1994, on the donation and use of elements and products of the human body, medically assisted procreation and prenatal diagnosis is also based on the general principle of prior consent (Article 1, 665 [11]) and anonymity (Article 1, 665[14]) of the donor and the gratuitous nature of the act (Article 1,665 [13]). Following an evaluation of the law’s implementation by the Parliamentary Office for the Assessment of Scientific and Technological Choices, it is to be re-examined by Parliament within a maximum period of five years following its entry into force i.e. in 1999.

A new Title I in the Code of Public Health establishes the general principles applicable to the donation and use of elements and products of the human body. The removal of elements and products of the human body and the collection of the products thereof may not be performed without the donor’s prior consent, which may be revoked by the donor at any time (Article 1,665 [10 and 11]).
The law also prohibits any form of advertising intended to promote donation of elements and products of the human body for the benefit of a specific person or for the benefit of a specific establishment or agency. However, such prohibition does not hinder the dissemination of information to the public in favour of donation provided it is undertaken under the responsibility of the Minister of Health (Article I, 665 [12]). The law prohibits payment in any form whatsoever to a person who submits to the removal of elements of his body or a collection of products thereof. Where appropriate, expenses incurred during such a process may be reimbursed, in accordance with procedures laid down by a decree, after consulting the “Conseil d’Etat”. The law also enshrines the anonymity of the donor vis à vis the recipient and vice versa. The only exception allowed by the law are cases of therapeutic necessity.

Any removal of elements of the human body or a collection of products thereof for therapeutic purposes are subject to the rules of safety regarding health defined by a decree made after consulting the “Conseil d’Etat”. Such rules include, in particular, tests for the detection of communicable diseases (Article L, 665 [15]). Such a decree must also determine the conditions for monitoring elements and products of the human body, products other than medicaments derived therefrom as well as medical devices incorporating them and, in particular, the information which must be transmitted by users and third parties (Article L, 665 [16]). In the case of minors, the law makes specific provisions for bone-marrow transplants between siblings. However, a committee of experts must examine each case and a minor can object to the procedure.

The law permits the extracting of tissue cells as well as products from cadavers if this is done for therapeutic or scientific purposes and within the judicial framework applicable to organ transplant. Any kind of sampling of tissues, cells and products from a minor or a protected major is strictly prohibited. In the case of medically assisted procreation, the law prohibits the in vitro conception of human embryos for research purposes. Experiments on the human embryo are permitted exceptionally for therapeutic reasons only. Detailed provisions are set out to regulate the necessity of a couple’s prior informed consent to such procedures.

The donation of gametes, spermatozoids or oocytes can only be undertaken by a donor who is part of a couple which has already procreated. His consent and the consent of the other part of the couple must be obtained in writing. All mixture of sperm is prohibited. The gametes of the same donor cannot deliberately lead to the birth of more than five offspring.

The law defines prenatal diagnosis as “medical practices to detect in utero particularly serious disorders in embryos or foetuses. It must be preceded by a medical consultation entailing genetic counselling” (Article L, 162[16]). Where a serious probability exists of giving birth to a child bearing a serious genetic disease recognised as incurable at the time the diagnosis is made, the law also admits pre-implantation genetic diagnosis from cells taken from the embryo in vitro. The probability of giving birth to such a child must be certified by a medical practitioner in an institution specialised in prenatal diagnosis. The diagnosis can only be carried out after it has been established that one of the parents possesses an anomaly responsible for the genetic anomaly in question (Article L, 162[17]). In order to avoid any risk of eugenic pre-selection, the diagnosis “may have no purpose other than identification of this disorder and the means for its prevention and treatment” (ibid.). The diagnosis must be undertaken only after the written consent of the parents, and must be conducted in an institution approved by the National Commission of Medicine and Biology. This supervisory Commission gives advice on all proposals made to undertake such tests and monitors all work undertaken by institutions and laboratories authorised to undertake such practices (Article L, 162[16]).
A new Title VI in the Code of Public Health entitled “Preventive medicine and genetic identification”, defines the instances where the examination of the genetic characteristics of a person or his identification by genetic fingerprinting can be carried out. According to this Title, such practices can be carried out “only for medical purposes or for scientific research and after having obtained the consent of the person concerned”. These conditions need not be fulfilled when such examination is part of a legal procedure (Article L.145/15). If an examination or identification is performed for medical purposes, consent shall be obtained in writing. Examinations or identification for the purposes of scientific research shall be regulated by the provisions of (Book II (b) of the Code). On an exceptional basis the consent of the person concerned may be withheld in his interest and with due regard to confidentiality if the study is undertaken for medical purposes. Consent may also be withheld if the identification of a person by genetic fingerprinting is sought for medical purposes.

The National Ethical Consultative Committee for the Life and Health Sciences is responsible for issuing opinions on the ethical issues raised by progress and knowledge in the fields of biology, medicine and health, and publishes recommendations on these subjects. The composition and organization of the Committee and the procedures whereby matters are to be referred to it are issued by decree after consulting the Conseil d'Etat (Article L.145/23).

- Decree no. 96-327 of 16 April 1996, regulates the import and export of organs, tissues and cells of the human body with the exception of gametes, and amends the Code of Public Health (“Journal officiel de la République française, Lois et décrets”, 18 April 1996, no. 92 pp. 5954-5957)


This decree inserts a new division 2 in the Code of Public Health entitled “Studies conducted on embryos in vitro”. This is viewed as an exceptional measure and may only be carried out for the following purposes:

1. to offer a direct advantage to the embryo concerned, particularly with a view to increasing the chances of successful implantation; and

2. to contribute to the improvement of the techniques of medically assisted procreation, through the development of knowledge concerning the physiology and pathology of human reproduction.

Furthermore no study may be carried out if its object is to change, or if it is likely to change, the genetic heritage of the embryo, or if it is likely to adversely affect its developmental capacities (Article R.152/8-1).

**Germany**


German Law for the Protection of Embryos of 1990 specifically prohibits the cloning of the human embryo. Anyone who artificially causes an embryo to develop “with the same genetic information another embryo, fetus, human being or deceased person is punishable with up to five years imprisonment or a fine” (Article 6).
Any attempts at the artificial alteration of germline cells is equally punishable, but the following exceptions are permitted:

(i) the artificial alteration of the genetic information of a germ cell situated outside the body, if any use of it for fertilisation has been ruled out,

(ii) the artificial alteration of the genetic information of a different body’s germ line cells, that have been removed from a dead embryo, from a human or from a deceased person, if it has been ruled out that that they will be transferred to an embryo, fetus or human being or a germ cell will originate from them;

(ii) innoculation, radiation, chemotherapy, or other treatment by which an alteration of the genetic information of germ line cells is not intended (Article 5 (4,i)).

The Law also specifically prohibits the improper use of reproduction technology, the improper use of human embryos and pre-selection of gender (Articles 1, 2 and 3). In that context, the following circumstances are considered as improper use of reproduction technology:

(i) transfer into a woman of an unfertilised egg cell produced by another woman;

(ii) attempts to fertilise artificially an egg cell for any purpose other than bringing about a pregnancy of the woman from whom the egg cell originated;

(iii) attempts by gamete intrafallopian transfer, to fertilise more than three egg cells within one treatment cycle;

(iv) attempts to fertilise more egg cells from a woman than may be transferred to her within one treatment cycle;

(v) removal of an embryo from a woman before the completion of implantation in uterus in order to transfer it to another woman or to use it for another purpose not serving its preservation;

(vi) surrogate practices i.e. attempts to carry out an artificial fertilization of a woman who is prepared to give up her child permanently after birth or to transfer a human embryo into her.

Furthermore the artificial penetration of a human egg cell by a human sperm cell and the transfer of a human sperm cell into a human egg cell artificially, without intending to bring about a pregnancy in a woman from whom the egg cell originated is prohibited.

The Law indicates as constituting improper use of human embryos the production outside the body or the removal from a woman before the completion of implantation in the uterus or the disposal or acquisition for a purpose not serving its preservation (Article 2 (1)) and the development of a human embryo to develop further outside the body for any purpose other than bringing about of a pregnancy (Article 2 (2)). The Law defines an embryo as “a human egg cell fertilised and capable of developing, from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assumed to be able to divide and to develop into an individual” (Article 7).

The Law also emphasises the strictly voluntary nature of participation in medical practices such as artificial fertilisation, or transfer of a human embryo into a woman, or the preservation of a human embryo, or a human egg cell which has already been penetrated by, or has artificially captured a human cell. Furthermore, these activities can only be undertaken by a qualified doctor (Articles 9, 10 and 11).
ICELAND

Iceland has adopted a law on artificial insemination (Law no. 55/1996 of 29 May 1996) and a law on patients’ rights (Law no. 74/1997 of 28 May 1997) both of which concern the principles to be found in the Universal Declaration on the Human Genome and Human Rights. Both laws refer to an ethical commission which has not yet been established.

INDIA

- Chapter IV of the Diagnostic Techniques (Regulation and Prevention of Misuse) Act of 1994 (see IDHL, 1995, vol. 46, no. 1, pp. 47-49) establishes a Central Supervisory Board, to be set up by the Central Government, whose functions include the following activities: advising the State Government on policy matters relating to the use of prenatal diagnostic techniques; raising public awareness about the practices of prenatal sex determination and female foeticide; and laying down a code of conduct to be observed by persons working at genetic counselling centres, genetic laboratories and genetic clinics (section 16).

By virtue of this Act, the Central Government is also empowered to appoint one or more authorities for each of the Union territories with the responsibility of granting, suspending or cancelling the registration of a genetic counselling centre, genetic laboratory or genetic clinic and of enforcing the standards prescribed for each establishment (section 17).

Any person, Organization, genetic counselling centre, genetic laboratory or genetic clinic:

1. found to be advertising, in any manner whatsoever, the availability of facilities for the purpose of prenatal sex determination in any genetic counselling centre, genetic laboratory, genetic clinic or any other place;

2. is deemed to be committing an offence punishable by up to three years imprisonment and a fine. An advertisement is defined by the law as including “any notice, circular, label, wrapper, or other document and also includes any visible representation made by means of any light, sound, smoke or gas” (section 22).

INDONESIA

The Indonesian authorities indicated the following: “The human genome is related to the development of human values, such as those that underlay the fundamental unity of all members of the human family: everyone has the right to be respected in dignity. Dignity makes it imperative not to reduce an individual to their genetic characteristics [...] in principle, Indonesia is not supporting any research treatment or diagnosis affecting the individual’s genome, which would lead to human cloning. Nevertheless, up to the present, the Indonesian Government has not yet produced any legislation or regulation on bioethics, particularly on the human genome.”

In this same letter, the Indonesian authorities also indicated that their national philosophy is based on human rights enshrined in the 1945 Constitution. A Human Rights Commission was created by Presidential Decree on 7 June 1993, and its functions were defined thus: to develop conditions conducive to the implementation of human rights based on Pancasila, the 1945 Constitution, the United Nations Charter and the Universal Declaration of Human Rights of 1948; to promote the protection of human rights to realize national development goals, that is the development of the Indonesian nation-state and the people as a whole.”
ITALY

The Italian authorities replied to the questionnaire and provided texts of pertinent legislation in Italy.

The Italian legislature has been discussing several draft laws prohibiting any form of human and animal cloning as well as the commercialisation and advertising of gametes and human embryos (see Preamble to Ordinance dated 5 March 1997).

However, since it appears that none of the laws will be adopted in the near future, a moratorium on such practices was established by two Ordinances in 1997 for an initial period of 90 days, periodically extended by an Act of Parliament. All centres, whether public or private, which practise medically-assisted procreation were obliged to provide the Ministry of Health, within a specified time limit after the issue of the moratorium, with a detailed breakdown of their operations, as well as the official names and addresses of such centres and their directors (Article 3 of the Ordinance).

JAPAN

The Japanese authorities informed UNESCO that the following guidelines have already been adopted as measures to implement the principles set forth in the Universal Declaration on the Human Genome and Human Rights: Guidelines for Gene Therapy Clinical Research in Universities (Notice no. 79, June 9, 1994, Ministry of Education, Science, Sports and Culture; Guidelines for Gene Therapy Clinical Research (Notice no. 23, February 8 1994, Ministry of Health and Welfare (see IDHL, 1995, vol. 46, no. 4). The above mentioned letter indicated that the purpose of these guidelines is to specify the matters necessary to ensure scientific validity and ethics, and promote the proper conduct of gene therapy clinical research in general and in universities.

Chapter 3 of the Guidelines for Gene Therapy Clinical Research ensures informed consent on the part of subjects participating in gene research. In order to protect human rights, subjects are chosen with careful regard to their health, age and ability to grant consent (Article 9). The informed consent is defined thus: subjects, or in specific cases their legal representatives, are entitled to be informed, to the greatest extent possible and in an accessible language, of the following:

- the purpose and method of gene therapy clinical research;
- the expected benefits and harm;
- the existence, nature, and expected benefit and harm of alternative treatment methods;
- that subjects will not be disadvantaged if they do not give consent to gene therapy clinical research;
- that subjects can terminate consent to gene therapy clinical research at any time after giving it;
- other matters necessary to protect the human rights of subjects" (Articles 9 & 70).

In cases where it is difficult to obtain the oral or written consent of a subject because of lack of ability to consent or other reasons, but it is reasonably expected that subjects will benefit from gene therapy clinical research, consent can be obtained in written form from a legal representative qualified to give consent on the subject's behalf. In such cases, a record of the consent and the records which indicate the relationship between consentor and consentee should be kept (Article10 para. 2).
The Guidelines for Gene Therapy Clinical Research also protect confidentiality of personal records: “Researchers, members of the review committee and the institution head shall not disclose personal secrets they come to know in the conduct of gene therapy clinical research without justifiable reason” (Article 24).

Japanese law specifically prohibits all “gene therapy clinical research for the purpose of genetically altering human germ cells and clinical therapy clinical research in which there is a possibility of genetic alteration of human germ cells” (Guidelines for Gene Therapy Clinical Research, Article 6). The protection of public health should be adequately considered in conducting such research (ibid., Article 7). The guidelines lay down detailed procedures to be complied with by participants in a research project. Each gene therapy research project is under the control and responsibility of a director who must prepare a project proposal and obtain the permission of the institution head before conducting the research (Articles 17.1, 17.2 and 18). Each institution also has a review committee which decides on the appropriateness of proposals brought before it by the institution head and monitors their progress (Article 16). The review committee is composed of medical professionals in molecular biology, cell biology, genetics, clinical pharmacology, pathology, professionals in areas of clinical medicine related to the diseases targeted by the planned gene therapy clinical research and legal specialists qualified to examine scientific and ethical issues related to the conduct of gene therapy clinical research (ibid., para. 2).

The transparency and impartiality of the review process is ensured by prohibiting any participating researcher to sit in on its review. Furthermore, the entire review process, including the organization of its activities, is recorded, preserved and kept open to the public (ibid., paras. 3 and 4).

A final report on the results is submitted for approval by the institution head and must contain the following elements: the purposes and the period during which the gene therapy clinical research was conducted; the name and address of the institution at which the research was conducted; the name of the director and researchers of the gene therapy clinical research project; and the results and a discussion of gene therapy clinical research (Article 19.1).

The opinion of the Minister of Health and Welfare regarding the research can be sought by the institution head (Article 20). In the event of serious problems, for example the death of subjects during the course of the research, the Minister must be informed immediately (Article 22.2).

The Guidelines for Gene Therapy Clinical Research encourage researchers to use any occasion to provide information and education on gene therapy and to make efforts to educate the public by promoting the disclosure of appropriate and accurate information to the public concerning actual or planned research (Articles 25 and 26).

The law defines “gene therapy” as “introducing genes or gene-transferred cells into the human body for the purposes of treating diseases and gene marking” (Article 2.1). It defines “gene marking” as “introducing genes or gene-transferred cells as a marker into the human body for the purposes of developing treatment methods of diseases” (Article 2.2).

In adopting the Guidelines for Gene Therapy Clinical Research the Health Sciences Council recognised that they were not exhaustive and would be supplemented and updated as knowledge increased and new methods of gene therapy developed. The Council also expressed the hope “that the guidelines would be made more complete by scientifically-based comments on each issue from each discipline” (see the “Preface” to the Guidelines cited in “News and Views”, IDHL, vol. 46, no. 4 p. 562).
According to the Jordanian Government, our image of a person is a reflection of cultural ideologies and of the basic structures of society. It was absolutely indispensable for the biological revolution to take account of human values (United Nations Doc. E/CN.4/1997/66, p. 3. para. 14). The Jordanian Government considers that progress and the evolution of the biological sciences should be in the interest of human beings and not contrary to these interests. Biology and law confront each other in population planning, genetics and genetic engineering.

The role of the law is to establish a distinction between medical practice and biological experimentation and to impose restrictions on the functioning of the latter. To this end, the State should take the necessary legislative measures to ensure that the law restricts and controls biological sciences to put the brakes on any scientific progress which threatens human values and creates legal and ethical problems.

It considers the recourse to genetic manipulation and genetic engineering for the purpose of altering a human being or arbitrarily determining their sex and destiny as a practice that is contrary to all human values.

Cloning has ethical, behavioural and social consequences for society because it seriously threatens the laws of nature, especially if cloning is limited to individuals with criminal tendencies or with particular characteristics (Source United Nations Doc. E/CN.4/1997/66, p. 11, para. 44 c, (d) and (e)).

Latvia


Luxembourg

Luxembourg has signed the Council of Europe Convention on the protection of human rights and the dignity of the human being regarding applications in biology and medicine and the Additional Protocol on the prohibition of human cloning. The National Consultative Committee of Ethics for the Life Sciences and Health is studying the articles of the Convention and its Additional Protocol and it is expected that they will be adopted and become part of national law after the Committee has issued its recommendations on the texts.

Mexico

The Mexican National Commission for UNESCO provided a report on the activities of its national committees on health, bioethics and human rights and considers that Mexican principles of health law generally coincide with the principles set forth in the Universal Declaration on the Human Genome and Human Rights.

As part of the measures undertaken to promote the principles of the Universal Declaration through education, the Human Rights National Commission published several publications on health and human rights issues, which have been distributed to schools and libraries. Furthermore, several discussions have been taking place concerning the Declaration and a general assembly of the National Academy of Bioethics is to take place in the near future to promote awareness of the principles of the Declaration.
NETHERLANDS


In January 1998, a Consultation document of the Human Genetic Advisory Commission (HGAC) and the Human Fertilisation and Embryo Authority (HFEA) recorded that "to the best of our knowledge at the time of publication no legislation relating to cloning exists in the Netherlands" (see report at page 31).

NEW ZEALAND

The authorities of New Zealand provided a summary of existing legislative measures and copies of legislative texts. New Zealand is currently considering the adoption of specific legislation prohibiting the cloning of human beings. It has not adopted any legislation to implement the principles of the Universal Declaration on the Human Genome and Human Rights "as legislative measures are already in place to protect the individual's rights in this regard".

The Code of Health and Disability Consumer Rights ensures that individuals are protected when receiving health services or when participating in research through:

- **Right 3** of this Code (entitled: Right to dignity and independence) ensures every consumer the "right to have services provided in a manner that respects the dignity and independence of the individual";

- **Right 4** (Right to services of an appropriate Standard) includes "the right to have services provided that comply with legal, professional, ethical and other relevant standards," "to have services provided in a manner consistent with his or her needs and that minimises the potential harm to and optimises the quality of life of that consumer";

- **Right 6**: the right to be fully informed;

- **Right 7**: the right to make an informed choice;

- **Right 9**: give informed consent and rights concerning teaching and research.

The Code also provides for legal enforcement of ethical standards and guidelines set by professional and other accredited ethics committees.

The right to information is defined in terms of what a reasonable consumer would expect to receive given his or her particular situation. The following conditions are taken into consideration:

- an explanation of his or her condition;
- an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option;
- notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval;
- any other information required by legal, professional, ethical and other relevant standards;
- the results of tests; and,
- the results of procedures. (Right 6).
Regarding the issues of informed choice and informed consent, *Right 7* states the following:

1) Services may be provided to a consumer only if that consumer makes an informed consent and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.

2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.

3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.

4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where:
   a) it is in the best interests of the consumer; and
   b) reasonable steps have been taken to ascertain the views of the consumer; and
   c) either,
      i) if the consumer’s views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
      ii) if the consumer’s views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.

5) Where informed consent to a health care procedure is required, it must be in writing if:
   a) the consumer is to participate in any research; or
   b) the procedure is experimental; or
   c) the consumer will be under general anaesthetic; or
   d) there is a significant risk of adverse effects on the consumer.

6) Every consumer has the right to refuse services and to withdraw consent to services.

7) Every consumer has a right to express a preference as to who will provide services and have that preference met where practicable.

8) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.

9) Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved, or utilised only with the informed consent of the consumer.

A detailed complaints procedure is available where consumers feel their rights under the Act have not been respected (*Right 10*). A provider has the burden of proving that he “has taken all reasonable actions in the circumstances to give effect to
the rights, and to comply with the duties, under the Code”. By the term “the circumstances” the text intends all the relevant circumstances, including the consumer’s clinical circumstances and the provider’s resource constraints.

The New Zealand Bill of Rights Act (1990) also protects the individual’s right not to be subjected to medical or scientific experimentation (section 10). This text stipulates that “every person has the right not to be subjected to medical or scientific experimentation without that person’s consent” and that every person has the right to refuse medical treatment (section 11).

Genetic information held by a health agency is considered as health information under the Health Information Privacy Code (1994), issued under section 46 of the Privacy Act (1993). It regulates the collection, use and disclosure of health information concerning identifiable individuals. Rule 10 of the Privacy Code places limits the use of health information for research purposes; the approval of an ethics committee must be obtained and information cannot be published in a form whereby any individual can be identified.

The Human Rights Act (1993) partially defines “disability” in the following terms: “any (...) other loss or abnormality of psychological, physiological or anatomical structure or function” and “the presence in the body of organisms capable of causing illness” (section 21.1h). The Act also prohibits discrimination on the grounds of such disability.

The Accident Rehabilitation and Compensation Insurance Act (no. 13, 1992) establishes an insurance-based scheme to rehabilitate and compensate in an equitable manner those persons who suffer personal injury in cases of “medical error” or “medical mishap” which qualify as “medical misadventure”. The term “medical error” is defined as the failure of a registered health professional to observe a standard of care and skill reasonably to be expected in the given circumstances. It is not qualified as an error solely because desired results are not achieved or because subsequent events show that different decisions might have produced better results.

“Medical mishap” is defined as an adverse consequence of treatment by or following the direction of a registered health professional properly given, wherein :

(a) the adverse consequence is severe ; and
(b) the likelihood of an adverse consequence when such treatment is properly administered is determined to be rare.

This second condition is qualified in the following terms: “likelihood that treatment of the kind that occurred would have the adverse consequence is considered to be rare only if the probability is that the adverse consequence would not occur in more than 1 per cent of cases where that treatment is given.”

The Accident Rehabilitation and Compensation Insurance Act further qualifies the issues of personal injury and compensation as follows:

“8. Where personal injury to a person results from medical error or medical mishap that occurs in a clinical trial, that personal injury shall constitute medical misadventure only where :

a) the trial
   i) has been approved by an ethics committee approved by the Health Research Council or the Director General of Health; and
   ii) the ethics committee has certified that it is satisfied that the trial is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out; or
b) the person has not agreed in writing to participate in the trial”.

For the purposes of subsection 8 of this section, the term treatment includes anything done or omitted as part of a clinical trial.

**NORWAY**

The Norwegian Ministry of Health and Social Legislation provided a summary of the existing legal situation in Norway in relation to the implementation of the principles in the *Universal Declaration on the Human Genome and Human Rights*.

The legislation cited below was obtained from other sources and is based on translations undertaken in Norway.

The main law regulating bioethics, genetics and technology is *Law no. 56 of 5 August 1994, on the medical use of biotechnology*. An amendment in March 1998 added a new chapter prohibiting human cloning. The 1994 law was adopted on the presumption that it would be re-evaluated after five years. An extensive evaluation of the professional ethical and legal protectionary aspects of the law is currently underway; (an Act on the Rights of Patients will be presented to Parliament in Autumn 1998 to regulate the doctor - patient relationship.

Research is regulated through a system of research ethical committees in each of the five health regions in Norway.

The question of patenting human genetic material has not been the subject of specific legislation in Norway but is subject to the general laws governing patents.

The question of compensation for damage resulting from genetic intervention will in Norway be subject to legislation on compensation in general. A separate arrangement compensating patients who suffer from damage resulting from treatment in hospitals exists.

Norway signed the *Council of Europe Convention on human rights and biomedicine* and *Additional Protocol on human rights and biomedicine and on the prohibition on cloning* respectively and presumes that there will be no need for further regulations to fulfil the conditions in the *Universal Declaration on the Human Genome and Human Rights* on the human genome and human rights.


*Law no. 56 on the medical use of biotechnology* repeals a previous 1987 law on artificial fertilisation and amends the Children’s Law of 1981. Its main scope is “to ensure that a medical application of biotechnology is utilized in the best interests of human beings in a society in which every person has his place. This shall take place in keeping with the principles of respect for human dignity, human rights, and personal integrity and without discrimination on the basis of genetic make up (arveanlegg) based on ethical norms embodied in our Western cultural heritage” and applies to the medical use of biotechnology in human beings (*Chapter I, Article 1[1 and 1.2]*). The law contains detailed provisions on the legal limitations imposed in the conduct of research on fertilised eggs, pre-implantation diagnosis and post-natal genetic testing. Research on fertilised eggs is prohibited (*Article 3[1]*). However, a genetic examination of a fertilised egg is possible prior to implantation in the uterus “in special cases involving serious hereditary disease with no possibility of treatment” (*Article 4[2]*). Examination of a fertilised egg for the purpose of selecting the sex of the child is also prohibited, except in special cases involving serious hereditary sex-linked diseases.
Law no. 56 stipulates that the human genetic make-up may only be altered by means of gene therapy of somatic cells for the treatment of serious diseases or in order to prevent the occurrence of such diseases. It further stipulates that treatment with a view to the alteration of the genetic make-up of fertilised eggs shall be prohibited (Article 7/1). Before any treatment may be undertaken, it requires the approval of the Ministry on the advice of the Biotechnology Board.

The prior consent of the person to be treated is required for any type of gene therapy and, in the case of subjects under sixteen, the consent of their parents or legal guardians is required (Article 7/3).

Biotechnology may be used for medical purposes only in establishments specifically approved for this purpose by the Ministry. The decision-granting approval is to specify which forms of medical biotechnology may be used by the establishment concerned. Section 8(2) stipulates that all approved establishments must submit written reports to the Ministry on their activities.

The Crown is responsible for appointing a Board - the Biotechnology Board - to issue opinions on matters covered by the law and on other questions related to biotechnology. The Board’s opinions are to be made public, unless the law requires that they be kept confidential.

**POLAND**

The Polish legal system does not contain any specific legislation dealing with the human genome. However, the Constitution of 1997 entrenches the principle of human dignity as inviolable.

The Constitution of 1997 recognises inherent and non inalienable dignity as a source of the freedom as well as human and citizen’s rights. Human dignity is non-viable and the obligation of public authority is to respect it. (see extract from a summary of the legal scenario governing bioethics in Poland, prepared by the Polish National Commission for UNESCO).

- The Law on the Physician’s Profession of 5 December 1996 (Law no. 28, item 152) promulgates rules on medical experiments (Articles 21-29) but does not provide any prohibitions covered by the Declaration (see ibid., Polish summary).

- The Code of Medical Ethics of 1991 as modified in 1993 obligates the physician as well as all other people with whom he/she collaborates to protect and strictly respect the confidentiality of all information contained or derived from patients or patients’ family members, DNA material or research (ibid.). Failure to respect the code may lead to the physician’s name being deleted from the register of practitioners.

**PORTUGAL**

The authorities of Portugal replied to the questionnaire by a letter dated 7 July 1998 and attached a list of legislation in force in the fields of bioethics, biotechnology and genetics. The texts of these legislations were not included.

**RUSSIAN FEDERATION**

A national committee of bioethics was created in 1992 composed of professionals in biology, medicine and the human sciences. It prepares recommendations concerning the necessity to exercise strict ethical control on medical experiments (Source E/CN.4/1995/74, p. 32 para. 141).
The Russian Federation, together with Belarus and Ukraine issued a joint policy statement concerning the conditions for exercising scientific activities. (Source E/CN.4/1995/74 p. 16, para. 74).

SLOVAK REPUBLIC

The authorities of the Slovak Republic indicated their intention to ratify the 1998 Council of Europe Additional Protocol on the Prohibition on Human Cloning in the near future, thereby making it part of domestic law.

SPAIN


- **Law no. 35/1988 on assisted reproduction procedures** explicitly prohibits embryo and oocyte cloning prescribing criminal sanctions against anyone conducting such practices.

- **Law no. 42/1988 of 28 December 1988, on the donation and use of human embryos and foetuses or their cells, tissues or organs.** This law includes provisions enabling the use of genetic technology for *in vitro* and *in vivo* prenatal diagnosis of genetic/hereditary diseases (“Boletín Oficial del Estado”, Gaceta de Madrid, 31 December 1988, no 314, pp. 36766-36767; IDHL, 1991 vol. 42(1), pp. 64-68).

SPAIN (CATALUNYA)


SWEDEN


The Committee has the task to foster ethical responsibility and the safe use of genetic technology in such a way as to protect human and animal health as well as the environment. The Committee is also responsible for the dissemination of knowledge on developments in genetic technology. It submits an annual report to the Government. advises on applications for licences for genetically modified organisms, maintains an awareness of projects that are likely to need particular ethical reflection or to entail risks and takes any required initiative in this connection. It also creates public awareness by informing the population of developments in this field in such a way as to stimulate interest in ethical and safety issues. It also draws attention to the need to train personnel working in this field.
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This Law applies to injuries sustained in connection with health and medical care administered in Sweden. For the purposes of the law, the term “patient” covers persons who are voluntary subjects in medical research or who are donors of organs or other biological material for transplantation or other medical purposes. Patients have a right to compensation for injuries. Care providers are obligated by law to take out insurance to cover such compensation. The law also lists the causes for injuries granting the right to compensation (section 6) and derogation’s from this right (section 7). The modalities for the determination of compensation for injuries sustained by patients are laid out in sections 8-11 and a Patient Injury Committee examines individual cases (section 17).

TUNISIA


- Decree of 3 September 1990, regulating scientific and medical experiments for medicines intended for humans states that all experiments must be in conformity with international human rights conventions and norms of medical ethics concerning experimentation on humans. All research on minors, physically or mentally handicapped, or on pregnant women or women who are breast-feeding is prohibited (Doc. E/CN.4/1997/66, p. 7, para. 32).

- Code of Medical Ethics of 1993 emphasises the necessity to respect moral and scientific principles in all research. Research on human subjects is prohibited if the benefit of the research is outweighed by the risk to the subject on which such research is performed. All foreseeable risks and advantages of such research for the subject must be carefully weighed (Doc. E/CN.4/1997/66, p. 9, para. 38).

- Decree of 19 September 1994 promulgated under the Public Health Law, created a national ethics committee to advise the Government on ethical problems concerning the individual and society. It also lays down guiding principles which seek to reconcile technological progress with ethical and legal norms, social, economic and cultural realities, human values and human rights (Doc. E/CN.4/1997/66, p. 3, para. 14).

UNITED KINGDOM

The authorities of the United Kingdom provided information on the Human Fertilisation and Embryology Act of 1990 and of Regulations establishing the Human Genetics Advisory Commission.

- Human Fertilisation and Embryology Act (1990)

The Human Fertilisation and Embryology Act regulates the creation, use and storage of human embryos outside the human body and sets up an Authority - the Human Fertilisation and Embryology Authority, (HFEA) - to oversee in vitro fertilisation, donor insemination and research involving the creation or use of human
embryos. Anyone undertaking an activity governed by the Act without an HFEA licence may be found guilty of a criminal offence (Articles 41 and 42). The HFEA also licenses all fertility treatments involving the use of embryos created outside the body (IVF); donated eggs or sperm (e.g. donor insemination); the storage of eggs, sperm and embryos; and all research on embryos (Articles 5-9). In addition to its licensing role, the HFEA has several other responsibilities including the publication of a Code of Practice giving guidance to centres on how they should carry out licensed activities (Articles 25 and 26); keeping a confidential register of information about donors, patients and treatments (Article 31-35); publicising its role and the services licensed centres provide; giving advice and information to licensed centres, the general public, people seeking fertility treatment, donors and people who may need to store sperm, eggs or embryos for medical reasons (Article 8); and reviewing the whole field of fertility treatment and research, whether the activities are licensed or not. It also makes recommendations to the Government upon request.

The Act defines the term 'embryo' as follows: "embryo means a live human embryo where fertilisation is complete", and "references to an embryo include an egg in the process of fertilisation, and for this purpose, fertilisation is not complete until the appearance of a two cell zygote" (Article 1.1a & b). The Act applies to bringing about the creation of an embryo outside the human body. The Act clarifies that and "references to embryos the creation of which was brought about in vitro (in their application to those where fertilisation is complete) are to those where fertilisation began outside the human body whether or not it was completed there" and that references to embryos taken from a woman do not include embryos whose creation was brought about in vitro. The Act also applies to keeping or using an embryo outside the human body (Article 1.3). It further applies to live human gametes, eggs or sperm, except where otherwise stated, but references in the Act to gametes or eggs do not include eggs in the process of fertilisation (Article 1.4).

The following activities in connection with embryos are prohibited under the Act:

"(...) No person shall:

a) bring about the creation of an embryo, or,
b) keep or use an embryo, except in pursuance of a licence.

No person shall place in a woman:

a) a live embryo other than a human embryo, or
b) any live gametes other than human gametes.

(...)"

3) A licence cannot authorise:

a) keeping or using an embryo after the appearance of the primitive streak, placing an embryo in any animal,

(...)"

b) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use, or
d) replacing a nucleus of a cell of an embryo with a nucleus taken from a cell of any person, embryo or subsequent development of an embryo".

4) For the purposes of '3(a)', above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day when the gametes are mixed, not counting any time during which the embryo is stored." (section 3)
Section 4 prohibits the storage or mixture of gametes without a licence or the use of sperm in the course of providing treatment unless the services are being provided to the woman and man together and in pursuance of a licence. The use of the eggs of any other woman in the course of treatment for a woman is also prohibited.

The Act permits research involving human embryos within strict limits which must not exceed the fourteenth day of their development under a licence from the HFEA. Embryos used for research must not be replaced in a uterus. The HFEA can license the use of human embryos only where it considers their use to be necessary for the research; therefore, animal studies must often have been carried out before research involving human embryos will be permitted.

In addition, any such research must appear to the HFEA to be necessary or desirable for one of the following purposes: to promote advances in the treatment of infertility; to increase knowledge about the causes of congenital disease or about the causes of miscarriage; or to develop more effective techniques of contraception or methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

According to Schedule 2 of the Act, the list may be extended by the Secretary of State for Health through regulations, provided that the new categories can only be established if their purpose is to increase knowledge either about the creation and development of embryos, or about disease, or with a view to enabling such knowledge to be applied.

HFEA’s policy is that it will not license any research which has reproductive cloning as its aim. However, it will consider licence applications for other types of research involving embryo splitting or nuclear replacement in eggs, provided that such research falls within one of the purposes specified in the HFEA Act, or any regulations which may be made by the Secretary of State for Health.

The “Preliminary Work” of the Act (see Warnock Committee report of the Committee of Inquiry into Human Fertilisation and Embryology, Her Majesty’s Stationary Office [HMSO] July 1984) did not intend human reproductive cloning to be permitted. Debate in the House of Commons showed a concern that the law needed to be reviewed to take account of scientific developments (see report of the House of Commons Science and Technology Committee, Session 1996-1997, Fifth Report of 18 March 1997, vol. [I]). The Government response has indicated that while human reproductive cloning cannot take place in the United Kingdom, it will consider carefully, in the light of developments, whether the legislation needs to be strengthened in any more specific way. It has said that, regarding cloning, it will take into account the views of Members of Parliament, the HGAC, HFEA and responses to any general consultation on the broader issues (see House of Commons Official Report, Parliamentary Debates Hansard, 26 June 1997, Column 615, cited in the consultation document issued by the HGAC and the HFEA entitled “Cloning issues in Reproduction, Science and Medicine” p. 12, para. 5[6]). The United Kingdom Minister for Public Health confirmed that work which would create cloned human beings should not and cannot lawfully be carried out and that “we regard the deliberate cloning of human individuals as ethically unacceptable”(ibid.).

The Human Fertilisation Embryology Authority Code of Practice as amended on 16 July 1998, introduces the concept of genetic testing of both gamete donors and patients. An Advisory Committee on Genetic Testing established in 1996 is currently discussing whether additional guidance on the subject should be produced, particularly regarding the information which should be provided to patients and donors, the accreditation of the laboratories which clinics employ to carry out genetic testing and, in the case of cystic fibrosis, the mutations which should be tested for.
Although the guidance is not intended to form part of the Code of Practice, it will assist clinics in complying with the new guidance (see explanatory letter to the revised Code of Practice from Chairman of the HFEA of 16 July 1998, to directors of clinics and HFEA Inspectors).

The Code amends the statutory period for storage of embryos and gametes as well as the regulations on their subsequent use, and it contains amendments on genetic testing, the practice of recruiting donors via agencies, expenses payable to egg donors, consent, information on the risks associated with treatment and with genetic testing, genetic counselling and the transfer of gametes and embryos between licensed clinics.

**United Kingdom (Isle of Man)**


**United States of America**


  The Act amends the Public Health Service Act by inserting a new subpart 3 (the national center for human genome research mentioned in *Part E of Title IV*). The center’s general purpose is to “characterize the structure and function of the human genome, including the mapping and sequencing of individual genes”, including planning and co-ordinating the research goal of the Human Genome Project (HGP); to co-ordinate international genome research; to communicate advances in genome science to the public; and to review proposals to address the ethical and legal issues associated with the HGP (including legal issues regarding patents).


  These guidelines supersede all earlier versions and specify the practices for constructing and handling:

  i) recombinant deoxyribonucleic acid (DNA) molecules; and

  ii) organisms and viruses containing recombinant DNA molecules.

  Some of the provisions deal with the transfer of recombinant DNA, etc. into one or more human subjects. It contains a detailed appendix entitled “Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into the Genome of One or More Human Subjects”. Included are sections dealing with research-design, anticipated risks and benefits, selection of patients; informed consent and privacy and confidentiality.


**United States of America, State of California**

The Act prohibits health-insurance companies from discriminating against policy holders or applicants for health-insurance policies on the basis of asymptomatic genetic characteristics.


The Executive Order 12975 established a National Bioethics Advisory Commission (NBAC) composed of a maximum of 15 Members appointed by the President of the United States of America to advise the National Science and Technology Council and other appropriate government entities on “the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines and regulations as they relate to bioethical issues arising from research on human biology and behaviour; and applications, including the clinical applications, of that research” (section 4, a [1 & 2]). The Commission issues advice on matters referred to it by the National Science and Technology Council, the Congress and the public. It may also, of its own initiative, submit advice and recommendations on bioethical issues it has identified, subject to the approval of the National Science and Technology Council. The protection of the rights and welfare of human research subjects and the management and use of genetic information, including human gene patenting, are considered as the NBAC’s first priority. In establishing other priorities for its activities, the following criteria should guide the NBAC:

(i) the public health or public policy urgency of the bioethical issue;

(ii) the relation of bioethical issues to the goals regarding federal investment in science and technology;

(iii) the absence of another entity able to deliberate appropriately on bioethical issues and the extent of interest in any given issue within the Federal Government (section 5 - Priorities).

The Order obliges all structures involved in research involving human subjects to review their existing policies to ensure that the protection of the rights and welfare of human research subjects is their first priority and to develop professional and public educational programs to enhance activities relating to the protection of human subjects (section 1 of Order 12975). This can take the form of seminars to address ongoing and emerging issues in research with human subjects, and of familiarising professionals engaged in non-federally funded research with the ethical considerations associated with conducting research involving human subjects (section 2 ibid.). The law also considers that where, appropriate, such professional and educational programmes should be organised and conducted with the participation of medical schools, universities, scientific societies, voluntary health organizations or other interested parties (ibid.).

An amendment concerning the protection of human subjects and informed consent was introduced to **Title 21 (Food and Drugs) of the United States Code of Federal Regulations of 17 July 1996**, (“Federal Register” vol. 61 no. 192, 2 October 1996, pp. 51498-51533; IDHL, 1997, vol. 481, pp. 47-48). In case of emergency research, a narrow exception to the requirement to obtain and document informed consent from each human subject, or the legally authorised representative, is allowed. The exception applies to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition and who do not have a legally authorised person to represent them.
In a report by the NBAC after it was called on to give advice on the ethics of cloning procedures, it concluded that using nuclear replacement technology for the purposes of creating a child was unsafe and recommended legislation to ban research into the cloning of "complete people". The President has withdrawn all federal funding for research concerning cloning of human beings.

The *Human Cloning Prohibition Act of February 3 1998* prohibits human cloning, and specifically the use of somatic nuclear transfer technology for the purposes of human cloning. The bill also prohibits the importation of cloned human embryos created by somatic cell nuclear transfer. The Bill also outlines criminal and civil penalties for violations of the prohibitions of human cloning or the importing of human clones; establishes a National Commission to Promote a National Dialogue on Bioethics; and protects other areas of genetic research that do not involve human cloning. The Sponsors of the Bill state that since the Bill’s prohibitions focus narrowly on cloning by somatic nuclear transfer, they would not interfere with important research such as gene therapy, the cloning of DNA, molecules, cells, tissues, plants and animals; stem-cell research or other work. The Bill states that nothing in it shall be construed to restrict areas of scientific research that are not specifically prohibited.