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**REPORT BY THE DIRECTOR-GENERAL ON THE DRAWING UP
OF A DECLARATION ON UNIVERSAL NORMS FOR BIOETHICS**

SUMMARY

Pursuant to 170 EX/Decision 3.5.1 and in accordance with the timetable approved by the Executive Board at its 169th session, the Director-General submits this progress report on the work carried out by UNESCO since the 170th session of the Executive Board concerning the drawing up of a declaration on universal norms for bioethics. The report contains in an annex the text of the preliminary draft declaration which was transmitted to the Director-General by the International Bioethics Committee (IBC) at the completion of its work.

Decision proposed: paragraph 41.

INTRODUCTION

1. Pursuant to 170 EX/Decision 3.5.1 and in accordance with the timetable approved by the Executive Board at its 169th session, the Director-General submits this progress report on the work carried out by UNESCO since the 170th session of the Executive Board concerning the drawing up of a declaration on universal norms for bioethics.

2. The document reports on the consultations carried out at the national and international level on the Third Outline of the text drawn up by the International Bioethics Committee (IBC); the work of the fifth and sixth meetings of the IBC Drafting Group and the work of the fourth session of the Intergovernmental Bioethics Committee (IGBC) (24-25 January 2005), of the joint session of IBC and IGBC (26-27 January 2005) and of the extraordinary session of IBC (28 January 2005), leading to the finalization of the preliminary draft declaration presented in annex to this document.¹

WRITTEN CONSULTATION ON THE THIRD OUTLINE OF THE DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

3. In accordance with the timetable, a broad international written consultation on the Third Outline of a Text (27 August 2004) – elaborated by the IBC Drafting Group immediately after the Eleventh Session of IBC (Paris, 23-24 August 2004) – was carried out by UNESCO between October and December 2004.

4. In order to receive comments or suggestions on the text and on issues that remained open, in particular on the way in which specific subjects could be dealt with in the text of the declaration, the Third Outline was sent – in English and French – to all Member States and Associate Members, to international organizations (the United Nations and its specialized agencies, more than 100 intergovernmental and non-governmental organizations) and relevant national bodies, in particular national ethics committees and to some 40 experts and eminent personalities, including former members of IBC. All the documents concerning the consultation were also made available on the Internet (www.unesco.org/bioethics) to provide the general public with an opportunity to contribute to the consultation.

5. As of 7 January 2005, the Secretariat had received 27 responses from Member States and one from a Permanent Observer, four from intergovernmental organizations, 14 from non-governmental organizations and institutes, 13 from national bioethics committees and 10 contributions in a personal capacity. In general terms, the comments reflect appreciation for the structure and the main lines of the text drawn up by IBC, while at the same time showing that positions remain divided on a certain number of issues which will certainly be subject to further reflection and discussions.

6. The preliminary results of the consultation were examined by the IBC Drafting Group at its sixth meeting (Paris, 12-14 December 2004) and an overview and analysis of the replies received as of 7 January 2005 was brought to the attention of the fourth session of IGBC, the joint session of IBC and IGBC and the extraordinary session of IBC in January 2005 (see below).

¹ All the documents and reports on the meetings mentioned in this document are available from the Bioethics Section of the Division of Ethics of Science and Technology and on the Internet (www.unesco.org/bioethics).

COOPERATION WITH THE OTHER INTERGOVERNMENTAL ORGANIZATIONS CONCERNED

7. In the framework of the dialogue and consultation with other international organizations, UNESCO hoped to include an item on the drawing up of the future declaration on the agenda of the fourth meeting of the United Nations Inter-Agency Committee on Bioethics, which was held at UNESCO Headquarters in Paris on 10 December 2004 and which was attended by representatives of the following organizations: the Office of the United Nations High Commissioner for Human Rights, the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), the European Commission, the Council of Europe, the Arab League Educational, Cultural and Scientific Organization (ALECSO), World Trade Organization (WTO) and the Organisation for Economic Cooperation and Development (OECD), and UNESCO.

8. The meeting provided an opportunity to meet the members of the IBC Drafting Group for an exchange of views on the Third Outline of the declaration. The organizations represented welcomed the transparency of the process under way and the efforts of the IBC Drafting Group to make further progress with the text.

9. Generally speaking, the participants acknowledged that the declaration was general in scope and was intended to lay down the major principles in the field of bioethics. Nevertheless, observations were made about the scope of the future declaration, some participants taking the view that the declaration should be limited to the life sciences in order to respect the areas of competence of other organizations. Others called for a clearer definition, in particular in the section on aims, of the beneficiaries of the declaration, be they individuals, the scientific community or government institutions.

10. It was also pointed out that the issue of human rights, duly reflected throughout the Third Outline, could more effectively accommodate individual rights.

11. More specific comments were directed at the article on consent, which did not seem to make a sufficiently clear distinction between the different situations in which consent must be obtained, in particular between consent in the field of research and consent in the area of medical diagnosis and treatment.

12. With regard to the article on risk assessment, the participants considered that the term “precautions” could be used without explicit reference to the principle of precaution, which is still a subject of discussion in the international community. Lastly, some participants wished to include a reference to the right to a healthy diet in the declaration.

CONSULTATIONS AT NATIONAL LEVEL

13. Within the “Ethics Around the World” project, several rotating conferences were organized in cooperation with respective National Commissions for UNESCO, namely in: Vilnius (Lithuania, September 2004), Ankara (Turkey, September 2004), Buenos Aires (Argentina, November 2004), Seoul (Republic of Korea, November 2004), Mexico City (Mexico, November 2004), Jakarta (Indonesia, December 2004), Lisbon (Portugal, January 2005) and Moscow (Russian Federation, January 2005). The reports of the above-mentioned conferences were provided to the IBC Drafting Group and made available on the Internet.

14. These conferences, held between September 2004 and January 2005, provided an opportunity to extend the consultation on the Third Outline to the national level. National experts from different disciplines – jurists, philosophers, doctors, researchers, social science specialists among others –

took part in the conferences. In general, the participants showed a clear wish for a common standard-setting framework in the field of bioethics and praised the efforts made by UNESCO and IBC in the drafting of the text. Critical and constructive remarks and suggestions were also expressed by the participants, referring *inter alia* to: the distinction among principles, the relationship between bioethics and human rights, the concept of the biosphere and the nature of attendant human responsibility, the special needs of developing countries and the link between bioethics and global problems such as access to quality health care, nutrition, drinking water, poverty and illiteracy, and the application and implementation of the future declaration.

WORK OF THE IBC DRAFTING GROUP

15. In the period under consideration, the IBC Drafting Group held two sessions, on 27 and 28 October and on 12 to 14 December 2004. It devoted its fifth meeting in October to a preliminary revision of the Third Outline. Those amendments were then reviewed at its sixth meeting in December in the light of, *inter alia*, the results of the written consultation, the debate held on the occasion of the fourth meeting of the United Nations Inter-Agency Committee on Bioethics and other international, regional and national meetings.

16. On the basis of the commentary of the members of IBC and proposals made on the occasion of the various consultations, the Drafting Group first held a general debate on the text, in particular on the structure of the principles laid down in it. The Group then examined the text article by article, clarifying and fleshing out the text, reformulating specific articles (for example, on scope and consent) and proposing new articles on, *inter alia*, the definitions and the principles of equality, justice and equity and social responsibility.

17. In the light of those modifications to the text, the Drafting Group considered it appropriate to recommend the wording “Universal Declaration on Bioethics and Human Rights” as the title of the future declaration, thus reflecting the emphasis placed on the link between bioethics and human rights.

18. At its sixth meeting, the Drafting Group completed a Fourth Outline of a declaration on universal norms on bioethics (15 December 2004), which was immediately made public and served as the working document for the fourth session of IGBC and the joint session of IBC and IGBC.

FOURTH SESSION OF IGBC, JOINT SESSION OF IBC AND IGBC AND EXTRAORDINARY SESSION OF IBC

19. The fourth session of IGBC was held at UNESCO Headquarters in Paris on 24 and 25 January 2005 and was followed immediately by a joint session of IBC and IGBC on 26 and 27 January, then by an extraordinary session of IBC on 28 January 2005.

20. That week of meetings brought together some 200 participants from 70 countries in all regions of the world – members of IBC, representatives of Member States, representatives of intergovernmental and non-governmental organizations, national ethics committees, experts and specialists. Most of the time was spent drawing up the future declaration, thus preparing the way for and facilitating the future work to be done by the government experts at their meetings and ensuring continuity between the work done by the independent experts of IBC and the work that would be done subsequently at the intergovernmental meetings of experts.

Fourth session of IGBC

21. The following Member States of IGBC were represented: Belgium, Brazil, Canada, Chile, China, Costa Rica, Egypt, Finland, France, Germany, Ghana, India, Indonesia, Islamic Republic of Iran, Italy, Libyan Arab Jamahiriya, Kenya, Latvia, Malawi, Mexico, Mozambique, Nigeria, Republic of Korea, Russian Federation, Saudi Arabia, Thailand, Togo, Tunisia, Uganda, United States of America, Uruguay and Venezuela. The Chairperson of IBC, Ms Michèle S. Jean (Canada), and the Chairperson of the IBC Drafting Group, Mr Michael Kirby (Australia), took part in the debates while many IBC members attended as observers.

22. In accordance with its agenda, the Intergovernmental Bioethics Committee first elected its Bureau, as follows:

Chairperson: Ms Cinzia Caporale (Italy)

Vice-Chairpersons: Mr Abdulaziz Mohammed Al-Swailem (Saudi Arabia)
Mr Elmar Grens (Latvia)
Mr Pablo Sader (Uruguay)
Mr Huanming Yang (China)

Rapporteur: Ms Esther Kakonge (Kenya)

23. The session was mainly devoted to the drawing up of the future declaration and to a discussion on the Fourth Outline of the text, as finalized by the IBC Drafting Group. The participants congratulated IBC on the work accomplished and welcomed the transparency of the process. Members of IGCB sought clarification of several points in the text. In particular, it appeared necessary to specify, first of all, the beneficiaries of the different provisions of the declaration and, secondly, to define the scope of the expression “any decision or practice”, a formulation that some wished to avoid.

24. While noting the quality of the text submitted, the participants pointed out that it could still be enriched and refined over the following months, not only within the framework of IBC’s proceedings but also during the intergovernmental meetings of experts to be held in 2005.

25. At its fourth session, on 25 January, IGBC adopted the following recommendations:

In relation to **item 7 “Elaboration of a Declaration on Universal Norms on Bioethics: Report on the Work of IBC and discussion on the Fourth Outline of a Declaration”**,

1. *Thanks and congratulates* the International Bioethics Committee (IBC) and its Drafting Group for the high quality of the work carried out in the framework of the elaboration of a declaration on universal norms on bioethics (32 C/Resolution 24);
2. *Welcomes* the efforts deployed by IBC and the Secretariat to ensure the transparency of the elaboration process of the draft declaration as well as the active participation of all stakeholders concerned in the framework of all consultations carried out throughout the elaboration process, in particular States, the United Nations and the other specialized agencies of the United Nations system, other intergovernmental and non-governmental organizations, appropriate national bodies and specialists;

3. *Also welcomes* the initiatives taken to foster dialogue between IBC and IGBC and to improve cooperation and interaction of their work;
4. *Takes note with satisfaction* of the substantial improvements that have led to the fourth outline and *appreciates* its spirit and structure;
5. *Considers nevertheless* that many crucial issues and principles need to be considered further, including but not limited to those related to autonomy, informed consent, social responsibility, risk assessment, sharing of benefits, transnational practices and ethics committees, and *invites* IBC, in the framework of the finalization of a preliminary draft declaration, to reconsider the relevant articles;
6. *Also invites* IBC to reconsider the provisions concerning the use of terms, scope, aims, implementation principles, procedures and promotion and implementation of the declaration, in order to clarify to whom various provisions apply and are addressed;
7. *Further invites* IBC *inter alia*:
 - (i) to reconsider the formulation of Article 5 on restrictions and its location in the text;
 - (ii) to reconsider the wording of the title of Article 8 as well as the formulation of Article 9;
 - (iii) to make an appropriate reference to the freedom of research; and
 - (iv) where appropriate, to bring language in line with other UNESCO instruments;
8. *Recognizes* the quality of the text elaborated by IBC and, subject to modifications which could be made on the basis of the discussions of the fourth session of IGBC and the joint session of IBC and IGBC (26-27 January 2005), *considers* that it will constitute an excellent basis for further governmental negotiations aiming at improving the draft declaration;
9. *Considers* that, at the meetings in April and June 2005, the government experts should attempt to finalize a draft that can be presented to the 33rd session of the General Conference of UNESCO in October 2005.

In relation to **item 9 “International Declaration on Human Genetic Data: Preliminary Exchange of view on a Plan of Action for its Implementation”**,

10. *Takes note* of the preliminary proposals of IBC for the implementation of the International Declaration on Human Genetic Data as basis for further reflection and *suggests* that the discussion be continued in the appropriate institutions and in Member States.

Joint session of IBC and IGBC

26. The Director-General convened the joint session in accordance with Rule 11.7 of the Statutes of IBC in order to “foster dialogue between the IBC and the IGBC on matters of mutual concern”, namely, the drawing up of the future declaration. By providing an opportunity for an exchange of views between the two committees, the joint session of IBC and IGBC helped to clarify and enlarge upon the commentaries and remarks of the Member States and to enrich the final reflections of IBC.

27. In addition to the remarks made and specific amendments proposed by the Member States with respect to the text as a whole as well as specific articles, the debates gave rise to a basic agreement as to the aims of the future declaration, which should be, primarily, to:

- (i) establish a certain number of principles and procedures enabling States to draw up legislation or policies in the field of bioethics;
- (ii) place scientific decisions and practice within the scope of, and ensure their compliance with, a set of universally acceptable general principles;
- (iii) lastly, encourage a sustained dialogue within civil society on the challenges of bioethics and of the sharing of knowledge in science and technology.

28. It emerged that limiting the scope of the declaration to human beings, recognizing them as an integral part of the biosphere with responsibilities towards other forms of life, represented the basis of a consensus acceptable to all, which took account of both the specific mandate of UNESCO and the discussions already under way in other international forums.

29. With regard to more specific subjects, the participants were in favour of the consensual approach adopted by IBC, involving a periodic review of the declaration and leaving the door open to the elaboration, on the basis of the principles laid down in the declaration, of other international instruments on more specific subjects. Nevertheless, some participants expressed the view that subjects such as access to health care should be mentioned in the text. In that regard, the idea of including the principle of social responsibility was favourably received because it made it possible to evoke, in the context of a reflection on standards for the protection of human rights, the questions of access to quality health care, adequate water and nutrition, poverty reduction or improvement of environmental conditions. The future declaration thus opened up possibilities for action in the field of bioethics that went further than the various professional codes of ethics concerned and reiterated the need to place bioethics in the context of overall political and social reflection.

30. With regard to the title of the future declaration, most of the participants did not want to keep the word “norms” because of the ambiguity to which it could give rise in the context of a declaration. There was, however, a divergence of opinion with regard to including a reference to human rights.

31. Lastly, some participants expressed their concern about the provision under which States Members would submit a report every five years in connection with the implementation of the declaration. While recognizing the value of a follow-up mechanism based on States’ reports, they pointed out that because the declaration was non-binding, such a mechanism could not be set up in the same manner as for UNESCO’s conventions and recommendations.

Extraordinary session of IBC

32. The extraordinary session of IBC was opened by the Director-General who paid tribute, in his address, to the work done by IBC and expressed his conviction that the government experts, during the forthcoming intergovernmental meetings (4-6 April and 21-23 June 2005), would make good use of their expertise to refine and finalize, on the basis of the work of IBC and the recommendations of IGBC, an innovative, consensual and high-quality draft declaration.

33. The session provided a final opportunity for observers to express publicly their views on the draft text and also enabled IBC, during restricted meetings, to finalize and approve the text of the preliminary draft declaration on universal norms on bioethics, which is contained in an annex to the present document.

34. During its finalization of the text, IBC examined all of the commentaries and specific amendments proposed by the Member States throughout the week of work. In view of the limited time available and the impossibility of reflecting all the views, some of them divergent, the Committee decided to amend the text only where a consensus had emerged among its members.

35. Concerning the structure of the text, the Committee decided to combine the sections on “implementation principles” and “procedures” into a single section entitled “conditions for implementation”. Similarly, it revised the articles on the definitions, the scope and the aims in an effort to eliminate the ambiguities linked to the expression “decision or practice”. With regard to the principles and other provisions of the text, in addition to the drafting changes, IBC endeavoured to find a balance between the general character of the statement of principles and the wish of some members to go into more detail on specific aspects (for example in the case of consent).

CONCLUSIONS

36. In line with 32 C/Resolution 24 adopted by the General Conference at its 32nd session in October 2003 and in accordance with the timetable approved by the Executive Board (169 EX/Decision 3.6.2), the process of drafting a declaration on universal norms on bioethics began in January 2004.

37. The first phase of the work to draw up the future declaration was marked by the transparency with which it was conducted and the greatest possible involvement of all concerned. While respecting the tight deadlines fixed, many consultations (in written form, in the form of conferences, etc.), which took place at the various stages in the drafting process and concerned the different versions of the text, were held at all levels (national, regional, international). Because the text was published regularly online, the process of drafting was made accessible to the greatest possible number.

38. Following a very tight schedule and after examining carefully the many commentaries from various sources on the different versions of the texts, at the end of a year of intensive work and after six meetings of its Drafting Group, the International Bioethics Committee (IBC) accomplished its mandate as a consultative committee of independent experts and approved, at its extraordinary session on 28 January 2005, the preliminary draft declaration.

39. Far from attempting to resolve all the existing bioethics issues, which are evolving daily, the text finalized by IBC aims to establish a certain number of principles and procedures that will enable States to develop legislation or policies in the field of bioethics. It also aims, in so far as possible, to place scientific decisions and practice within the scope of, and ensure their compliance with, a set of universally accepted general principles. Lastly, it aims to encourage a sustained dialogue within civil society on the challenges of bioethics and of the sharing of knowledge in science and technology.

40. The preliminary draft declaration has been transmitted to the Member States in preparation for the work of the intergovernmental meetings of experts (category II) which, in accordance with 170 EX/Decision 3.5.1, have been convened by the Director-General for 4 to 6 April and 21 to 23 June 2005, with a view to enriching the present text and finalizing a draft declaration on universal norms on bioethics.

Proposed draft decision

41. After examining this report and in light of the above, the Executive Board may wish to adopt a decision along the following lines:

The Executive Board,

1. Recalling 170 EX/Decision 3.5.1,
2. Bearing in mind the timetable for the drawing up of the declaration on universal norms on bioethics that it approved at its 169th session (169 EX/Decision 3.6.2),
3. Having examined document 171 EX/13,
4. Having taken note of the recommendations of the fourth session of the Intergovernmental Bioethics Committee (IGBC) with regard to the drawing up of the declaration,
5. Thanks and congratulates the International Bioethics Committee (IBC) and its Drafting Group for the superlative work accomplished;
6. Reiterates its satisfaction at the open and transparent process of preparation of the future declaration and at the efforts to ensure the active participation of all concerned in the framework of all the consultations held throughout the process;
7. Recognizes the quality of the preliminary draft drawn up by IBC, which is contained in the annex to document 171 EX/13, and considers that it constitutes an excellent basis for the governmental negotiations aimed at finalizing the draft declaration;
8. Considers that the government experts, during the meeting of 25 June 2005, should finalize and present a draft to the Director-General with a view to its transmission to the 33rd session of the General Conference of UNESCO in October 2005.

ANNEX

**PRELIMINARY DRAFT DECLARATION
ON UNIVERSAL NORMS ON BIOETHICS**

This Preliminary Draft Declaration on Universal Norms on Bioethics was finalized by the International Bioethics Committee (IBC) at its Extraordinary Session on 28 January 2005 after six meetings of its Drafting Group held between April and December 2004, three sessions of IBC (April 2004, August 2004, January 2005), two written consultations (January-March 2004 and October-December 2004), numerous consultations at international, regional and national levels (including within the framework of the United Nations Inter-agency Committee on Bioethics), a session of the Intergovernmental Bioethics Committee (IGBC) and a joint session of IBC and IGBC (January 2005).

Recommended title:

Universal Declaration on Bioethics and Human Rights

The General Conference,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment; to perceive injustice; to avoid danger; to assume responsibility; to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the inherent dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for the human species and for the biosphere,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,

Also recalling the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on

the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Recommendation of UNESCO on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),

Bearing in mind international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1989, 1993, 1996, 2000 and 2002 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences adopted in 1982 and amended in 1993 and 2002,

Considering that, by virtue of its Constitution, it is incumbent upon UNESCO to promote the democratic principles of the dignity, equality and respect of human beings and to reject any doctrine of inequality, and that this constitutes a duty which all nations must fulfil in a spirit of mutual assistance,

Considering also UNESCO's role in developing universal principles based on shared ethical values to guide scientific and technological development and social transformation, in order to identify emerging challenges in science and technology taking into account the responsibility of the present generation towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere and that they have responsibilities and duties towards each other and towards other forms of life,

Recognizing that scientific and technological developments have been, and can be, of great benefit to humankind in increasing *inter alia* life expectancy and improving quality of life and emphasizing that such developments should always promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the inherent dignity of the human person and the universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that bioethical issues may have an impact on individuals, families, groups or communities and humankind as a whole,

Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary for humankind and, in this sense, is the common heritage of humanity, but emphasizing that it may not be invoked to contravene fundamental human rights and freedoms,

Convinced that ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play today a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the need for a new approach to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity and to the interest of humanity,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account in particular the special needs of developing countries,

Proclaims the principles that follow and adopts the present Declaration.

GENERAL PROVISIONS

Article 1 – Use of Terms

For the purpose of this Declaration:

- (i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;
- (ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and
- (iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.

Article 2 – Scope

The principles set out in this Declaration apply as appropriate and relevant:

- (i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and
- (ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.

Article 3 – Aims

The aims of this Declaration are:

- (i) to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned;

- (ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law;
- (iii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;
- (iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, policy-makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;
- (v) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
- (vi) to recognize the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and
- (vii) to safeguard and promote the interests of the present and future generations.

PRINCIPLES

Article 4 – Human Dignity and Human Rights

- (a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms;
- (b) Any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society.

Article 5 – Equality, Justice and Equity

Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably.

Article 6 – Benefit and Harm

Any decision or practice shall seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice.

Article 7 – Respect for Cultural Diversity and Pluralism

Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.

Article 8 – Non-Discrimination and Non-Stigmatization

In any decision or practice, no one shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.

Article 9 – Autonomy and Individual Responsibility

Any decision or practice shall respect the autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others.

Article 10 – Informed Consent

- (a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.
- (b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.
- (c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration.

Article 11 – Privacy and Confidentiality

Any decision or practice shall be made or carried out with respect for the privacy of the persons concerned and the confidentiality of their personal information. Unless irretrievably unlinked to an identifiable person, such information shall not be used or disclosed for purposes other than those for which it was collected.

Article 12 – Solidarity and Cooperation

Any decision or practice shall pay due regard to solidarity among human beings and encourage international cooperation to that end.

Article 13 – Social Responsibility

Any decision or practice shall ensure that progress in science and technology contributes, wherever possible, to the common good, including in the achievement of goals such as:

- (i) access to quality health care and essential medicines, including for reproductive health and the health of children;
- (ii) access to adequate nutrition and water;
- (iii) improvement of living conditions and the environment;
- (iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and
- (v) reduction of poverty and illiteracy.

Article 14 – Sharing of Benefits

- (a) Benefits resulting from scientific research and its applications shall be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
- (i) special and sustainable assistance to the persons and groups that have taken part in the research;
 - (ii) access to quality health care;
 - (iii) provision of new diagnostics, facilities for new treatments or medical products stemming from the research;
 - (iv) support for health services;
 - (v) access to scientific and technological knowledge;
 - (vi) capacity-building facilities for research purposes; and
 - (vii) any other form consistent with the principles set out in this Declaration.
- (b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.

Article 15 – Responsibility towards the Biosphere

Any decision or practice shall have regard to its impact on all forms of life and their interconnections and to the special responsibility of human beings for the protection of the environment, biodiversity and the biosphere.

CONDITIONS FOR IMPLEMENTATION

Article 16 – Decision-Making

Any decision or practice should:

- (i) be made or carried out following full and free discussion and in accordance with fair procedures;
- (ii) be made or carried out on the best available scientific evidence and methodology;
- (iii) pay due regard to any different information on the subject reasonably available to the decision-maker;
- (iv) be considered rigorously and based on the principles set out in this Declaration;
- (v) observe, when appropriate, proper procedures of risk assessment, management and prevention; and
- (vi) be considered individually, having regard to the circumstances of the persons, groups and communities concerned.

Article 17 – Honesty and Integrity

Any decision or practice should be made or carried out with:

- (i) professionalism, honesty and integrity;
- (ii) declaration of all conflicts of interest; and
- (iii) due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society.

Article 18 – Transparency

Any decision or practice should, subject to the provisions on privacy and confidentiality in Article 11:

- (i) be made or carried out transparently and openly;
- (ii) be available for appropriate scrutiny by the persons concerned and by civil society; and
- (iii) be susceptible to informed, wide and pluralistic public debate.

Article 19 – Periodic Review

Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with:

- (i) persons affected by any such decision or practice;
- (ii) members of relevant disciplines;
- (iii) appropriate bodies; and
- (iv) civil society.

Article 20 – Ethics Committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

- (i) assess the ethical, legal and social issues related to scientific research projects involving human beings;
- (ii) formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration, in accordance with the principles set out herein; and
- (iii) foster debate and education in bioethics.

Article 21 – Promoting Public Debate

States should promote opportunities for informed, pluralistic public debate, ensuring the participation of all persons and bodies concerned, including relevant ethics committees and non-

governmental organizations, and the expression of various sociocultural, religious, philosophical and other relevant opinions.

Article 22 – Risk Assessment, Management and Prevention

- (a) When evidence of serious or irreversible damage to public health or human welfare becomes available, appropriate measures should be taken in a timely manner.
- (b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms.

Article 23 – Transnational Practices

- (a) States should take appropriate measures to ensure that any activity with bioethical implications, which is undertaken in whole or in part in different States, complies with the principles of this Declaration. Public and private institutions and professionals associated with a transnational activity should also take all appropriate measures to achieve the same end.
- (b) When research is carried out in one country and funded partially or wholly by sources from one or more other countries, such research should be subjected to ethical review in all of the countries involved. This review should be based on ethical and legal standards, consistent with the principles set out in this Declaration, adopted by the States concerned.

IMPLEMENTATION AND PROMOTION OF THE DECLARATION

Article 24 – Role of States

- (a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information. States should also take appropriate measures to involve young people in these activities.
- (b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, in accordance with Article 20.
- (c) States should establish processes for the assessment, management and prevention of risks. Such processes should include the identification of the issues, the characterization of risks and benefits, the development of options, the implementation of the decisions and the monitoring of the results.

Article 25 – Bioethics Education, Training and Information

- (a) In order to implement and promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments,

States should endeavour to foster all forms of bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

- (b) States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 26 – International Cooperation

- (a) States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.
- (b) Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.
- (c) States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 27 – Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

- (a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out herein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, in particular on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.
- (b) Reports provided by States, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO.

Article 28 – Follow-up action by UNESCO

- (a) UNESCO shall take appropriate action to follow up this Declaration by evaluating new developments in science and technology and their applications according to the principles set out herein.
- (b) UNESCO shall reaffirm its commitment to dealing with the ethical aspects of the biosphere and, if necessary, shall endeavour to elaborate guidelines and international instruments, as appropriate, on ethical principles related to the environment and other living organisms.
- (c) Five years after its adoption and thereafter on a periodical basis, UNESCO shall take appropriate measures to examine this Declaration in the light of scientific and technological development and, if necessary, to ensure its revision, in accordance with UNESCO's statutory procedures.

- (d) With respect to the principles set forth herein, this Declaration may be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.

OPERATION OF THE PRINCIPLES AND DECLARATION

Article 29 – Interrelation and Complementarity of the Principles

In their interpretation and application, the principles set out in this Declaration are complementary and interrelated and each principle should be construed in the context of the other principles. Where there is conflict between the principles this should be resolved by balancing all those principles that are appropriate and relevant in the circumstances.

Article 30 – Restrictions on the Principles

No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law, and which are consistent with international human rights law and necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.

Article 31 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.