

Hundred and seventieth Session

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

SUMMARY

Pursuant to 169 EX/Decision 3.6.2 and in accordance with the timetable approved by the Executive Board at its 169th session in the same decision, the Director-General submits this progress report on the work carried out by UNESCO concerning the drawing up of a declaration on universal norms on bioethics.

An addendum to this document will contain the outline of the text of the declaration drafted by the International Bioethics Committee at its eleventh session (23-24 August 2004) and the decision proposed to the Executive Board thereon.

INTRODUCTION

1. Pursuant to 169 EX/Decision 3.6.2 and in accordance with the timetable that the Executive Board approved at its 169th session in the same decision, the Director-General submits this document which reports on the progress achieved in drawing up a declaration on universal norms on bioethics.
2. The document contains, in particular, the results of the consultations held on the scope and structure of the future declaration, including the written consultation of Member States and the extraordinary session of the International Bioethics Committee (IBC) (UNESCO Headquarters, 27-29 April 2004); the work of the IBC Drafting Group responsible for drawing up the text of the future declaration; the information meeting of the Intergovernmental Bioethics Committee (UNESCO Headquarters, 7 July 2004); and the initiatives taken to involve the other intergovernmental organizations concerned.¹
3. An addendum to this document will provide the main lines of the outline of the declaration drafted by the International Bioethics Committee at its eleventh session (UNESCO Headquarters, 23-24 August 2004) and the decision proposed to the Executive Board on the subject.

RESULTS OF THE WRITTEN CONSULTATION OF MEMBER STATES

4. The first written consultation of UNESCO Member States, Associate Member States and Permanent Observer Missions was launched on 20 January 2004 in the form of a questionnaire, in English and French, and a document outlining the general context of this new undertaking. The questionnaire was composed of three parts: the first focusing on the aims and objectives of the declaration, the second on its structure and the third on its content.
5. On 24 May 2004, the Secretariat had received 67 official replies from Member States, including seven from the Africa region, eight from the Asia and the Pacific region, 10 from the Arab States region, 21 from the Europe and North America region, 10 from the Central and Eastern Europe region, six from the Latin America and the Caribbean region and one from a Permanent Observer.
6. Those replies generally appeared to favour the drafting of a text that was broad in scope and not limited to humankind: 83% of the questionnaires expressed the wish that the declaration would cover ethical issues relating to genetically modified organisms, 80% that it would deal with biodiversity, 92% that it would contain provisions on the use of animals in transplantations and 80% that it would make reference to the environment.
7. The large majority of States were in favour of a structure comprising a preamble followed by sections. Among the fundamental principles most often mentioned by States were confidentiality, consent, respect for human dignity and transparency. A number of States also mentioned the importance of principles linked to the right to life, the rights of the child, equity and tolerance. Lastly, the vast majority of the replies suggested that the declaration should make reference to specific subjects. Opinions are still highly divided, however, on some subjects such as abortion, euthanasia, intellectual property rights and behavioural research. It is therefore stressed in the

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).

general comments that the declaration ought to be one of general principles that could be the object of a large consensus.²

8. A summary of the replies received was submitted to IBC at its extraordinary session (Paris, 27-29 April 2004) and was brought to the attention of the United Nations Inter-Agency Committee on Bioethics at its third meeting (Paris, 24-25 June 2004) and of the Intergovernmental Bioethics Committee (IGBC) on the occasion of the information meeting of 7 July 2004.

EXTRAORDINARY SESSION OF IBC (PARIS, 27-29 APRIL 2004)

9. Entrusted by the Director-General with the first stages of the process of drawing up the declaration and, aware of the importance of involving the main actors in this vast undertaking, IBC decided to organize an extraordinary session entitled “Towards a Declaration on Universal Norms on Bioethics”, held at UNESCO Headquarters in Paris from 27 to 29 April 2004. Opened by the Director-General, that extraordinary session brought together more than 200 participants from more than 70 countries.

10. The aim of the session was to hold consultations with the actors concerned, initiating a debate on the scope and structure of the future declaration. The session was thus organized into hearings of representatives of three different groups – intergovernmental organizations, international non-governmental organizations and national bioethics committees – followed by a question-and-answer session with IBC members and the audience.

11. Among the intergovernmental organizations invited to give an oral presentation at the session, the following organizations replied favourably: European Commission, Council of Europe, Office of the High Commissioner for Human Rights, Arab League Educational, Cultural and Scientific Organization (ALECSO), World Intellectual Property Organization (WIPO), Food and Agriculture Organization of the United Nations (FAO), Organisation for Economic Co-operation and Development (OECD) and United Nations University (UNU). The United Nations Office of Legal Affairs was also represented.

12. The following non-governmental organizations and national bioethics committees were invited to give an oral presentation:

- World Medical Association (WMA), World Association of Children’s Friends (AMADE) (unable to attend), International Council for Science (ICSU), Development Alternatives with Women for a New Era (DAWN) (unable to attend), Disabled People’s International (DPI), International Federation of Human Rights (FIDH) (absent), Human Genome Organization (HUGO) and International Association of Bioethics (IAB);
- National Consultative Bioethics Committee of Côte d’Ivoire, National Bioethics Committee for Medicine of Croatia, National Bioethics Committee of Egypt, President’s Council on Bioethics of the United States of America, National Bioethics Committee of the Academy of Sciences of the Russian Federation, National Consultative Ethics Committee of France, Bioethics Committee of the Council of Science and Technology of Japan, National Bioethics Committee of Mexico, National Council of Ethics for Life Sciences of Portugal, Korean Bioethics Association, National Bioethics Committee of the Democratic Republic of the Congo, National Bioethics Committee of the Dominican Republic,

² All the documents relating to the consultation and its results are available from the Bioethics Section of the Division of Ethics of Science and Technology and on the Internet (www.unesco.org/bioethics).

Nuffield Council on Bioethics of the United Kingdom and National Medical Ethics Committee of Tunisia.

13. Approximately 15 other non-governmental organizations and 15 other national bioethics committees and similar bodies also took part in that meeting. All organizations and institutions were invited to submit written contributions in advance, thereby providing IBC with a comprehensive overview of all the ideas and opinions expressed.

14. All speakers considered that the drafting of this new declaration afforded an opportunity to reflect on a common ethical framework for the life sciences as a benchmark for all: for States as well as the scientific community, patients and families, decision-makers, citizens and the media alike. Furthermore, it should contribute to better awareness of the ethical issues raised by scientific advances and their application. Some participants hoped that the declaration would become as authoritative in the field of science and technology as the Universal Declaration on Human Rights (1948) had become.

15. As to the question of whether the declaration should be limited or not to human beings, some contributors deemed it impossible to dissociate human beings from their environment (plants and animals). On the other hand, others felt that the field of application should be oriented towards human beings. It was suggested that the declaration should first of all address ethical issues relating to human beings and then, if desired, address ethical questions concerning the relationship between human beings and other living organisms. For example, it could be reaffirmed in the preamble that human beings are a key element of biodiversity and that their well-being and development remain intimately linked to the ecosystem in which they live.

16. Regarding the structure of the declaration, all participants wanted the text to consist of a preamble and clear, precise sections. The preamble would place the spirit and the issues of the future declaration into a philosophical, cultural and international legal framework.

17. In regard to the content of the declaration, preference was expressed for a text that was general in scope, and some considered that the declaration should be designed as a means of interpreting the basic principles of bioethics. It might nevertheless be appropriate, in some contexts, to make reference to a principle's practical applications.

18. With respect to the norms and values which should underpin the drafting of the declaration, the speakers stressed in particular the principles of human dignity, human rights, cultural diversity and the protection of fundamental rights and freedoms. In addition, themes such as equity, justice, international cooperation, solidarity, benefit-sharing, and also education and equal access to health care, which are key concerns for developing countries, should necessarily figure in a declaration purporting to be universally applicable, as should a specific reference to women and the disabled.

19. In the context of North-South relations in the field of the life sciences, it was suggested that the declaration should address international and transnational research, taking into account current practices relating, for instance, to the donation of human organs, an issue that developing countries faced. Some participants expressed the view that States should be urged to conclude bilateral and multilateral agreements in order to build capacities in developing countries and encourage the sharing of scientific knowledge and expertise in all scientific fields. Lastly, the importance of procedural principles and mechanisms relating to technology transfers, free access to data and the establishment of ethics committees, such as the principle of responsibility or transparency, was broadly emphasized.

20. With regard to the implementation of the declaration, participants unanimously proposed to include the arrangements for educational, training, awareness-raising and information activities to be carried out at all levels. Mechanisms to follow up the application of the declaration and facilitate international coordination of the various existing international legal instruments on bioethics were also discussed.

CONSULTATIONS AT THE NATIONAL LEVEL

21. Under the “Ethics around the world” project, the first travelling conference was held in The Hague (Netherlands) on 18 March 2004, in cooperation with the Netherlands National Commission for UNESCO, followed by a second in Hamadan (Islamic Republic of Iran) on 2 May 2004, organized in cooperation with the Iranian National Commission for UNESCO and Avicenna University.

22. National experts from different disciplines – jurists, philosophers, doctors, researchers, social science specialists among others – took part in the conferences. After a plenary meeting outlining the future declaration’s background, mission and drafting procedures, the participants joined workshops based on the questionnaire on the scope and structure of the future declaration, drawn up for the consultation of Member States.

23. Despite divergences of opinion, the discussions and appraisals that characterized both conferences showed a clear wish for a common standard-setting framework in the field of bioethics. For all that, the question of whether a single instrument broad in scope or an instrument limited to humankind should be drawn up remained open.

24. The reports of the above-mentioned conferences were provided to the IBC Drafting Group responsible for drawing up a preliminary outline of the declaration. Other travelling conferences have already been scheduled to take place between September and December 2004 and will provide an opportunity to continue the consultations at the national level on the outline that will be finalized by IBC at its eleventh session (Paris, 23-24 August 2004) (see document 170 EX/9 Add.).

WORK OF THE IBC DRAFTING GROUP

25. At its extraordinary session (Paris, 27-29 April 2004), IBC formed a drafting group responsible for drawing up the declaration, initially composed of a small number of IBC members. All the members of the Committee were nonetheless requested to contribute actively to the work, through both their expertise and actual participation, as some had expressed the wish to join the Drafting Group at a later stage.

26. The Drafting Group, chaired by Judge Michael Kirby (Australia), and whose membership will be extended to other members of IBC as work on drawing up the text progresses, comprises the following members: Mr Leonardo De Castro (Philippines), Mr Donald Evans (New Zealand), Mr Hans Galjaard (Netherlands), Ms Yolanda Gómez Sánchez (Spain), Mr Héctor Gros Espiell (Uruguay), Ms Nouzha Guessous-Idrissi (Morocco), Ms Michèle S. Jean (Canada), Mr Michael Kirby (Australia), Ms Regine Kollek (Germany), Mr Takayuki Morisaki (Japan), Mr Edmund Pellegrino (United States of America), Mr Michel Revel (Israel) and Mr Patrick Robinson (Jamaica).

27. The Drafting Group met three times at UNESCO Headquarters in Paris, on 30 April, 2 and 3 June and 8 and 9 July 2004 respectively. During the meetings, the Group drafted a preliminary outline of the text, taking into account the results of the written consultation of Member States, the

comments and observations made at the extraordinary session, the third meeting of the United Nations Inter-Agency Committee on Bioethics (see paras. 39-43) and the IGBC information meeting (see paras. 33-38).

28. Throughout its work, the Drafting Group stressed the need to devise a common ethical framework, while upholding the plurality of views, cultures, traditions and beliefs.

29. With regard to the scope of the declaration, it was reiterated that a distinction should be made between the subject of rights – the human being – and the object of rights – animals and plants – towards which the subject of rights has obligations. While recognizing that the human being is an element of biodiversity, some members drew attention to a risk of conflict of competence with other organizations of the United Nations system, as well as with the feasibility studies in progress for the formulation of guidelines on subjects such as the environment in the framework of UNESCO's programme of ethics of science and technology (see in this respect 169 EX/Decision 3.6.1). The Drafting Group therefore agreed to focus primarily on the human being, while leaving open the possibility, if necessary, of referring to other fields and/or of covering them in the future.

30. At its first three meetings, the Group began to draft a preliminary outline of the text of the declaration, the provisional structure of which is as follows:

Preamble It establishes the framework within which the instrument lies. In keeping with the usual practice, the first part is devoted to the international legal context while the second part recalls the philosophical, scientific and political context within which the declaration falls.

Definitions The Group decided to deal with this part when the text will be at the finalization stage in order to determine whether definitions are necessary, it being understood that definitions would be limited to scientific terms.

Scope This part specifies that the principles set forth in the declaration apply to human beings, while recognizing the responsibilities and the duties of human beings towards other forms of life.

Aims This part illustrates all the goals targeted in the principles set forth in the declaration, which include providing a universal framework of fundamental principles and basic procedures to guide States in the formulation of their legislation and their policies in the field of bioethics, ensuring respect for human dignity and the protection of human rights and fundamental freedoms in the sphere of bioethics, recognizing the great benefits derived from scientific and technological development, fostering dialogue between all actors in bioethics, promoting the sharing of benefits and knowledge and safeguarding the interests of present and future generations.

General principles This part is designed to set out the basic principles that should underpin every decision and practice in the field of bioethics, including: respect for human dignity, human rights and justice; the responsibility and obligations of the human being towards the biosphere; respect for diversity and the principle of tolerance, which may not, however, be invoked to infringe human dignity and human rights or to limit the scope of the declaration; the principle of solidarity, equity and cooperation; and the principle of beneficence.

Implications of the general principles This part might include, *inter alia*, the principles of the primacy of the human person, non-discrimination and non-stigmatization, autonomy, consent, confidentiality, the right to information, the right to health care, and benefit-sharing.

Specific issues This part, the scope of which has not yet been defined, is designed to apply the principles set out in the declaration on specific issues, such as scientific research.

Procedural principles This part will deal with appropriate methods and procedures for reflection and decision-making in bioethics, for example the need for transparent and democratic procedures, the establishment of national bioethics committees and similar bodies, and the regulation of transnational practices.

Promotion and implementation Finally, the aim of this part is to ensure, at different levels, the application of the declaration and the principles set forth therein. It will thus address education and awareness-raising, international solidarity and cooperation, a reporting mechanism and an evaluation and periodic revision system, as the declaration might also be supplemented and extended by the drafting of new standard-setting instruments.

INFORMATION MEETING OF THE INTERGOVERNMENTAL BIOETHICS COMMITTEE (IGBC) (PARIS, 7 JULY 2004)

31. In accordance with the timetable approved by the Executive Board, a meeting to inform the Intergovernmental Bioethics Committee (IGBC) of the progress achieved in drawing up a declaration on universal norms on bioethics, in which the members of the IBC Drafting Group also participated, was held at UNESCO Headquarters on 7 July 2004.

32. The meeting brought together more than 100 participants and its aim was to inform IGBC of the progress of the work and to receive IGBC's views on the ongoing discussions, by inviting it to give an opinion on the text drawn up by the IBC Drafting Group to prevent any divergence between IGBC's debates and those of IBC.

33. The participants congratulated IBC on the work accomplished and commended the transparency of the work carried out by IBC. They also emphasized that the text could be improved and expanded over the coming months, not only in the framework of IBC's work but also on the occasion of the meetings of governmental experts to be convened in 2005.

34. As to the scope of the future declaration, given the deadlines set for drafting the text and the need to take into account the field of competence of other intergovernmental organizations, some participants considered that the scope of the future declaration should be limited to human beings. Others considered that issues relating to animals, plants and, more broadly, the biosphere should also be covered by the declaration. In any event, all agreed that it was necessary to draw up a text that was general in scope, recalling the basic principles of the international protection of human rights and fundamental freedoms. The declaration could also be supplemented by new instruments on more specific issues.

35. The participants initiated a discussion on the use of the term "norms", some expressing a preference for the term "principles". It was pointed out that a declaration, albeit non-binding in nature, was a standard-setting instrument in its own right, setting out the provisions that States undertake to implement.

36. Lastly, the mechanisms envisaged for promoting and implementing the declaration, particularly those for periodic reporting, evaluation and revision, were commended by the participants, but on condition that there would be no increase in the number of UNESCO bodies.

COOPERATION WITH THE OTHER INTERGOVERNMENTAL ORGANIZATIONS CONCERNED

37. The timetable for drawing up the declaration places great emphasis on consultations with the other intergovernmental organizations concerned. The consultations had previously begun on the occasion of the second meeting of the United Nations Inter-Agency Committee on Bioethics in November 2003 and were continued at IBC's extraordinary session in April 2004 (see paras. 9-20).

38. Immediately after the extraordinary session of IBC and pursuant to 169 EX/Decision 3.6.2, the Director-General sought to confirm his commitment to dialogue and cooperation among international organizations in the field of bioethics by inviting the heads of the other intergovernmental organizations concerned to pursue actively their collaboration with UNESCO in drawing up the future declaration.

39. In that connection, UNESCO requested that the drawing up of the future declaration be placed on the agenda of the third meeting of the United Nations Inter-Agency Committee on Bioethics (Paris, 24-25 June 2004), which was attended by the representatives of the Food and Agriculture Organization of the United Nations (FAO), the World Intellectual Property Organization (WIPO), the World Health Organization (WHO), the United Nations University (UNU), the Arab League Educational, Cultural and Scientific Organization (ALECSO), the European Commission, the Council of Europe, the Organisation for Economic Co-operation and Development (OECD) and UNESCO. That meeting, in which the Chairperson of IBC Ms Michèle S. Jean took part, provided an opportunity to bring the work of the IBC Drafting Group to the Committee's attention.

40. At the third meeting of the Inter-Agency Committee, the participants reiterated their full support for the drawing up of a declaration providing a universal ethical framework in the field of science and technology. They also welcomed the emphasis placed on the reference to the biosphere, while seeking clarification about the scope of the declaration, especially as regards issues relating to the human being. Strong emphasis was placed on the importance of respect for cultural diversity and of responsibility towards future generations. Similarly, the participants suggested that great emphasis should be placed in the future declaration on the principle of consent and responsibility, and on the right to safe food and a healthy environment.

41. At the end of the third meeting and on the proposal of UNESCO, the Inter-Agency Committee decided to include in the agenda of its fourth meeting, which will be held in December 2004 at UNESCO Headquarters in Paris, an item on the outline of the future declaration produced by IBC at its eleventh session (23-24 August 2004). The fourth meeting may afford an opportunity to organize a meeting between the Inter-Agency Committee and the IBC Drafting Group to exchange views on the outline of the future declaration.

CONCLUSIONS

42. The first phase of work to draw up the future declaration on universal norms on bioethics was characterized on the one hand by the greatest possible involvement of all the actors concerned from the earliest stages of the drafting of the text and, on the other hand, by the transparency of the consultation process followed by IBC and its Drafting Group.

43. The results of the Drafting Group's work, gradually disseminated and publicized (www.unesco.org/bioethics), should not be regarded as final but as stages in the overall process of drafting by the Drafting Group and IBC.

44. In accordance with the timetable approved by the Executive Board, IBC will hold its eleventh session at UNESCO Headquarters in Paris on 23 and 24 August 2004, followed by the fourth meeting of the Drafting Group. The eleventh session will be devoted entirely to the drafting of the future declaration on universal norms on bioethics and to the examination of the Drafting Group's work in that regard. The results of the eleventh session and the outline of the declaration that will be further developed by IBC on that occasion will be issued as an addendum to this document.

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

ADDENDUM

SUMMARY

This addendum complements the report of the Director-General (170 EX/9) on a declaration on universal norms on bioethics. It reports on the proceedings of the eleventh session of the International Bioethics Committee (Paris, 23-24 August 2004) and the fourth meeting of the IBC Drafting Group (Paris, 25-27 August 2004), and contains in an annex the text of the declaration finalized by IBC on that occasion.

In addition, in accordance with Article 21 of the Regulations for the general classification of the various categories of meetings convened by UNESCO, the Director-General submits to the Executive Board proposals concerning the decision to be taken by the Board on invitations to the government expert meetings (category II) that the Director-General intends to convene in 2005, in line with the timetable for the drawing up of the declaration approved by the Executive Board (169 EX/Decision 3.6.2).

Decision proposed: paragraph 22.

I. PROCEEDINGS OF THE ELEVENTH SESSION OF THE INTERNATIONAL BIOETHICS COMMITTEE (IBC)

1. The eleventh session of the International Bioethics Committee (IBC) (Paris, 23-24 August 2004), which was opened in the presence of the Director-General of UNESCO, was attended by approximately 250 participants from some 80 countries from every region of the world – members of IBC, representatives of Member States, of intergovernmental and non-governmental organizations and of national bioethics committees, experts and specialists, and representatives of young people and the media.

2. The eleventh session was devoted in particular to work on drawing up the future declaration on universal norms on bioethics. It featured hearings of representatives of the various religious and spiritual approaches. Six speakers from, respectively, the Buddhist, Catholic, Confucian, Hindu, Islamic and Jewish traditions were invited to take the floor. Each speaker gave a presentation based on his or her perception of the current challenges in bioethics and commented on the text prepared by the Drafting Group.

3. The debates gave rise to a productive exchange between the speakers, observers and IBC. The speakers stressed the need to pay particular attention to the points of agreement and the divergences between the different spiritual traditions. The discussions also underscored the importance the future declaration should give to issues related to the family, solidarity among individuals and the relationship of individuals to their environment, and to the rights, responsibilities and duties of individuals.

4. In accordance with the agenda, IBC then examined the second outline of the text of the future declaration drafted by the IBC Drafting Group (27 July 2004). The discussion concerned the various parts of the text, and in particular suggested new avenues of thought for the drafting work to come. For instance, it was recommended that the role played by civil society in the debate on bioethics should have a more prominent place in the text. Furthermore, a discussion took place on whether it was appropriate to use the term “norms” in the title of the declaration, with some speakers stating that such a notion might contradict the non-binding nature of the planned declaration.

5. Concerning the scope and thematic coverage of the future declaration, it was suggested, given the drafting deadlines, that consideration should be given to making provision for UNESCO, and IBC in particular, to carry out, in the future, more in-depth studies on specific questions that might lead to other international instruments.

6. In accordance with the agenda, it was at the eleventh session that IBC was to elect its Bureau. The Committee decided to maintain the membership of the Bureau as it stood until the twelfth session in autumn 2005 but to elect two new members to the vacant posts of Vice-Chairperson and Rapporteur. The Bureau is accordingly composed as follows:

Chairperson:	Ms Michèle Jean (Canada)
Vice-Chairpersons:	Mr Leonardo de Castro (Philippines)
	Mr Alphonse Elungu (Democratic Republic of the Congo)
	Ms Nouzha Guessous Idrissi (Morocco)
	Mr Patrick Robinson (Jamaica)
Rapporteur:	Mr Claude Huriet (France)

7. At its fourth meeting, which was held immediately after the eleventh session of IBC, from 25 to 27 August 2004, and in which a large number of other members of the Committee participated, the Drafting Group focused on revising part of the text of the second outline on the basis of the comments, observations and proposals made at the eleventh session, and developing those parts of the text that were not yet fully drafted. The finalized outline is contained in an annex to this document.

INVITATIONS TO THE GOVERNMENT EXPERT MEETINGS RESPONSIBLE FOR FINALIZING A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

8. In accordance with the timetable for drawing up a declaration on universal norms on bioethics, approved by the Executive Board at its 169th session (169 EX/Decision 3.6.2), the Director-General submits his proposals concerning invitations to the government expert meetings intended to advance the finalization of a declaration on universal norms on bioethics.

9. Pursuant to the “Regulations for the classification of the various categories of meetings convened by UNESCO” (hereinafter referred to as “the Regulations”), this meeting comes within the category of “intergovernmental meetings other than international conferences of States” (category II), and the chief participants will accordingly represent their governments.

10. Under the Regulations applicable to category II meetings, it is for the Executive Board to decide on the issuing of invitations to this meeting.

(a) Member States and Associate Members

11. Under Article 21 of the Regulations, the Executive Board, on the Director-General’s proposal and subject to the applicable regulating provisions, shall decide on the Member States and Associate Members whose governments are to be invited to this category of meetings (category II).

12. Under Article 23 of the Regulations, an invitation to governments of Member States and Associate Members to participate carries with it the right to vote.

(b) Non-Member States

13. Under Article 21, paragraph 3, of the Regulations, the Executive Board may designate non-Member States to be invited to send observers to the meeting.

14. The Director-General proposes that States that are not members of UNESCO but are members of at least one organization of the United Nations system be invited to send observers to the meeting of government experts. At the time of drafting this document, the list of such States was as follows: Brunei Darussalam, Holy See, Liechtenstein and Singapore. In addition, the Director-General proposes to the Executive Board that those States which become members of any United Nations system organization before the opening of the meeting be invited to attend the meeting as observers.

Palestine

15. Under Article 7B of the Regulations, the Executive Board may invite Palestine to send observers to the meetings of government experts.

(c) International organizations

- The United Nations and other organizations in the United Nations system with which UNESCO has concluded agreements providing for mutual representation

16. The Director-General reminds the Board that, under Article 21, paragraph 4, of the Regulations, the organizations of the United Nations system with which UNESCO has concluded mutual representation agreements may send representatives to the meetings of government experts.

Those organizations are the following:

United Nations (UN):

Economic Commission for Africa (ECA)
 Economic Commission for Europe (ECE)
 Economic Commission for Latin America and the Caribbean (ECLAC)
 Economic and Social Commission for Asia and the Pacific (ESCAP)
 Economic and Social Commission for Western Asia (ESCWA)
 United Nations Conference on Trade and Development (UNCTAD)
 United Nations Children's Fund (UNICEF)
 Office of the United Nations High Commissioner for Human Rights
 United Nations Development Programme (UNDP)
 United Nations Environment Programme (UNEP)
 United Nations Population Fund (UNFPA)
 World Food Programme (WFP)
 United Nations University (UNU)
 United Nations Institute for Training and Research (UNITAR)

Specialized agencies:

International Labour Organization (ILO)
 Food and Agriculture Organization of the United Nations (FAO)
 World Health Organization (WHO)
 United Nations Industrial Development Organization (UNIDO)
 World Intellectual Property Organization (WIPO)
 International Atomic Energy Agency (IAEA)

- Other international organizations

17. Pursuant to Article 21, paragraph 5, of the Regulations, the Director-General proposes that the following organizations be invited to send observers to the meetings of government experts:

- (i) *Organizations of the United Nations system with which UNESCO has not concluded an agreement providing for reciprocal representation*

World Trade Organization (WTO)

- (ii) *Other intergovernmental organizations*

Intergovernmental Agency of the Francophonie
 International Centre for Genetic Engineering and Biotechnology (ICGEB)
 European Commission
 Commonwealth of Independent States (CIS)

Council of Europe
Caribbean Council for Science and Technology (CCST)
Nordic Council
Latin American Faculty of Social Sciences (FLACSO)
Federation of Arab Scientific Research Councils (FASRC)
League of Arab States
African Intellectual Property Organization (AIPO)
Arab League Educational, Cultural and Scientific Organization (ALECSO)
Organisation for Economic Cooperation and Development (OECD)
Organization of the Islamic Conference (OIC)
Organization of American States (OAS)
Organization of Ibero-American States for Education, Science and Culture (OEI)
Pan-American Health Organization (PAHO)
African Union (AU)
Islamic Educational, Scientific and Cultural Organization (ISESCO)
Organization for Security and Cooperation in Europe (OSCE)
Andean Parliament
Latin American Parliament
Commonwealth Secretariat
Executive Secretariat of the Andrés Bello Convention (SECAB)
Latin Union

(d) International non-governmental organizations

(i) International non-governmental organizations maintaining formal associate relations with UNESCO

International Council for Philosophy and Humanistic Studies (ICPHS)
International Council for Engineering and Technology (ICET)
International Social Science Council (ISSC)
International Council of Scientific Unions (ICSU)
Education International

(ii) International non-governmental organizations maintaining formal consultative relations with UNESCO

Latin American Social Sciences Council (CLACSO)
Council for International Organizations of Medical Sciences (CIOMS)
International Federation of University Women (IFUW)
International Planned Parenthood Federation (FIPF)
World Federation of Teachers' Unions (FISE)
Inclusion International
Catholic International Education Office (OIEC)
Arab Lawyers' Union (ALU)

(iii) Networks admitted to consultative relations with UNESCO

European Academy of Arts, Sciences and Humanities (EAASH)
Club of Rome
International Cell Research Organization (ICRO)

(iv) *International non-governmental organizations and bodies maintaining operational relations with UNESCO*

Academia Europaea
International Association of Democratic Lawyers (IADL)
Latin American Association for Human Rights (ALDHU)
World Association of Industrial and Technological Research Organizations
International Commission of Jurists (ICJ)
International Federation of Catholic Universities (IFCU)
World Federation of Scientific Workers (WFSW)
Disabled People's International
Pax Christi International
Pax Romana - International Catholic Movement for Intellectual and Cultural Affairs (ICMICA)
International Humanist and Ethical Union (IHEU)

(v) *International non-governmental organizations and bodies maintaining relations with UNESCO in another framework*

Parliamentary Assembly of the Francophonie (APF)
Third World Network of Scientific Organizations (TWNSO)

(vi) *International non-governmental organizations and bodies not maintaining formal relations with UNESCO*

World Academy of Biomedical Technologies (WABT)
Law Association for Asia and the Pacific (LAWASIA)
World Medical Association (WMA)
International Association of Bioethics (IAB)
International Council of Women
World Federation for Mental Health
Handicap International
Human Genome Organization (HUGO)
International Union of Biological Sciences (IUBS)
Universal Movement for Scientific Responsibility (MURS)
International Society of Bioethics (SIBI)

18. Finally, in view of the issues to be addressed by the future universal declaration, the Director-General takes the view that invitations could be extended to bodies which may contribute to the work of the group of government experts, such as national ethics committees, academies of science, and so on.

CONCLUSIONS

19. The outline of the declaration on universal norms on bioethics (27 August 2004) annexed to this report is the outcome of the preliminary examination by IBC at its eleventh session (Paris, 23-24 August 2004) and discussions at the fourth meeting of the IBC Drafting Group (Paris, 25-27 August 2004).

20. The outline, in its current form, will be added to and refined by the IBC Drafting Group and IBC as a whole before being considered by the Intergovernmental Bioethics Committee (IGBC)

and, in its final form, transmitted to Member States for consideration at meetings of governmental experts, the purpose being to finalize a draft declaration.

21. In accordance with the timetable approved by the Executive Board, the outline will also be the subject of a written consultation with Member States, IGOs, NGOs, national bioethics committees, academies of science, and so on (between September and December 2004) and national and regional consultations under the “Ethics around the world” project. In addition, the fourth meeting of the United Nations Inter-Agency Committee on Bioethics, which will be held in December 2004 at UNESCO Headquarters in Paris, will provide an opportunity for the intergovernmental organizations members of the Committee to look again at the text of the future declaration.

22. The Executive Board, after examining this report and taking into account the foregoing observations, may wish to adopt a decision along the following lines:

The Executive Board,

1. Bearing in mind the timetable for drawing up the declaration on universal norms on bioethics which it approved at its 169th session (169 EX/Decision 3.6.2),
2. Having considered documents 170 EX/9 and 170 EX/9 Add. and its annex,
3. Congratulates the International Bioethics Committee (IBC) and particularly its Drafting Group for the quality of the work carried out;
4. Takes note with satisfaction of the open and transparent process of preparation of the future declaration and welcomes the efforts made to involve United Nations agencies, including FAO, WHO, WIPO and WTO, and other intergovernmental organizations concerned with bioethics in the preparatory process;
5. Invites the Director-General to continue preparatory work on a declaration on universal norms on bioethics and to report to it at its 171st session;
6. Further invites the Director-General to convene in 2005 meetings of government experts (category II) aimed at finalizing a draft of the declaration;
7. Decides:
 - (a) that invitations to participate, with the right to vote, in the meetings of government experts (category II) held to finalize a draft declaration on universal norms on bioethics will be extended to all Member States and Associate Members of UNESCO;
 - (b) that invitations to send observers to the meetings, as defined above, will be extended to the States mentioned in paragraph 14 of document 170 EX/9 Add.;
 - (c) that an invitation to send observers to the meetings, as defined above, will be sent to Palestine, as stated in paragraph 15 of document 170 EX/9 Add.;
 - (d) that invitations to send observers to the meetings, as defined above, will be sent to the organizations of the United Nations system which are listed in paragraph 16 of document 170 EX/9 Add.;

- (e) that invitations to send observers to the meetings, as defined above, will be sent to the intergovernmental and international non-governmental organizations which are listed in paragraph 17 of document 170 EX/9 Add.;
- (f) that the Director-General is authorized to issue any additional invitation that he may deem conducive to the work of the group of government experts, informing the Executive Board thereof.

**ELABORATION OF THE DECLARATION ON UNIVERSAL NORMS ON BIOETHICS:
THIRD OUTLINE OF A TEXT**

This third version of an outline of a declaration on universal norms on bioethics was elaborated by the Drafting Group of the International Bioethics Committee at its Fourth Meeting (Paris, 25-27 August 2004), held in Paris from 25 to 27 August 2004, immediately after the eleventh session of IBC (Paris, 23-24 August 2004). This outline is not complete. It is not to be considered definite but as a step in the drafting process of the Drafting Group and the IBC in its entirety.

DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

OR

**UNIVERSAL DECLARATION ON BIOETHICS
AND HUMANITY [HUMANKIND/HUMAN BEINGS]***

The General Conference,

Recalling 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 Universal Declaration of Human Rights of 10 December 1948, 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 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 the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system,

Also recalling 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 the other international and regional instruments, national legislation and regulations in the field of bioethics,

Also recalling the international and regional codes of conduct and guidelines and other ethical texts in the field of science and technology,

* The words in [square brackets] offer variants of the wording concerned.

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

Considering also that it is the mission of UNESCO to develop universal principles and norms based on shared values to guide scientific and technological development and social transformation, in order to meet emerging challenges in science taking into account the responsibility of the present towards future generations,

Bearing in mind UNESCO’s activities and programmes in the field of natural, social and human sciences, aiming at placing scientific and technological development in a context of ethical reflection, and at promoting the sustainable use and conservation of biological diversity and the improvement of the relationship between human beings and their environment,

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

Recognizing that scientific and technological developments have been 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 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,

Bearing in mind that, without prejudice to the universal respect for, and observance of human rights and fundamental freedoms, cultural diversity, as a source of exchange, innovation and creativity, is necessary for humankind and, in this sense, it is the common heritage of humanity,

Convinced that ethical reflection is an integral part of scientific and technological development and that bioethics plays today a predominant role in the social choices that need to be made,

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

Considering that questions of bioethics raised by advances in science and technology, which have been addressed in part by the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, should be treated as a whole, drawing on the principles already affirmed in these two international instruments and taking account not only of the current scientific context but also of future developments,

Proclaims the principles that follow and adopts the present Declaration.

[USE OF TERMS]

(LIMITED TO SCIENTIFIC TERMS)

GENERAL PROVISIONS

Article 1 – Scope

The principles set out in this Declaration:

- (i) apply to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere; and
- (ii) apply to issues raised by scientific and technological developments and their applications, as well as their availability and access.

Article 2 – Aims

The aims of this Declaration are:

- to provide a universal framework of fundamental principles and basic procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned;
- to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision-making, in accordance with human rights law;
- to promote respect for biodiversity;
- to recognize the great benefit derived from scientific and technological developments, while ensuring that such development occurs within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms, and to prevent practices contrary to human dignity;
- to foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy-makers and society as a whole;
- to promote the sharing and the greatest possible flow of knowledge concerning scientific and technological developments as well as the sharing of benefits, in particular with developing countries;
- to safeguard the interests of present and future generations.

GENERAL [FUNDAMENTAL] PRINCIPLES

Article 3 – Human Dignity, Human Rights and Justice

Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms and for the universal principle of justice.

Article 4 – Beneficence and Non-Maleficence

Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice [to the persons concerned].

Article 5 – Respect for Cultural Diversity and Pluralism

Any decision or practice within the scope of this Declaration shall take into account the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious beliefs and like considerations. However, cultural diversity [such considerations] shall not be invoked to infringe upon the universal principles set out in this Declaration, nor to limit their scope.

Article 6 – Solidarity, Equity and Cooperation

Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure equity and encourage international cooperation [, in order *inter alia* to avoid discrimination and stigmatization of an individual, a family or a group].

Article 7 – Responsibility towards the Biosphere

Any decision or practice within the scope of this Declaration shall have due regard for their impact on all forms of life and their interconnection and the special responsibility of human beings for the protection of biodiversity and the biosphere within which human beings exist.

DERIVED PRINCIPLES

Article 8 – Primacy of the Human Person

Any decision or practice within the scope of this Declaration shall be founded on the recognition of the primacy of the human person, which shall prevail over the [sole] interest of science or society.

Article 9 – Non-Discrimination and Non-Stigmatization

In any decision or practice within the scope of this Declaration, no one shall be subjected to discrimination based on any grounds, including physical, mental or social conditions, diseases or genetic characteristics, nor shall such conditions or characteristics be used [invoked] to stigmatize an individual, a family or a group.

Article 10 – Autonomy and Responsibility

Any decision or practice within the scope of this Declaration shall respect the autonomy of a person as an expression of his/her liberty to make decisions without prejudice to the autonomy of others.

Article 11 – [Informed] Consent

(a) The prior, free, informed and express consent of the persons concerned shall be obtained in all medical or scientific research, treatment or diagnosis. Such consent may be withdrawn at any time.

(b) When, in accordance with domestic law consistent with international human rights law, a person is incapable of giving consent, such consent [authorization] should be obtained from his/her legal representative, having regard to the best interest of the person concerned.

Article 12 – Privacy and Confidentiality

Any decision or practice within the scope of this Declaration shall be made or carried out with [full] respect for the privacy of the persons concerned and the confidentiality of their personal information. Such information cannot be used or disclosed for purposes other than those for which

it was collected, except with the consent of the person concerned or in cases restrictively provided for by domestic law consistent with international human rights law.

Article 13 – Sharing of Benefits

In accordance with international and domestic law, benefits resulting from scientific research and their applications should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms:

- (i) special assistance to the persons and groups that have taken part in the research;
- (ii) access to medical care;
- (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research;
- (iv) support for health services;
- (v) access to scientific and technological knowledge, in particular for developing countries;
- (vi) capacity-building facilities for research purposes;
- (vii) any other form consistent with the principles set out in this Declaration.

PROCEDURAL PRINCIPLES

Article 14 – Honesty and Integrity

Any decision or practice within the scope of this Declaration shall:

- (i) be conducted with independence and intellectual honesty;
- (ii) respect the need for integrity in scientific and other research;
- (iii) avoid conflict of interest and duty; and
- (iv) pay 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 15 – Transparency and Openness

Any decision or practice within the scope of this Declaration shall:

- (i) be made transparently and openly;
- (ii) be determined with particular regard to the circumstances known to the persons concerned;
- (iii) be subject to respect for privacy and confidentiality [, as stated in Article];
- (iv) be available for appropriate scrutiny by the persons concerned and by civil society; and
- (v) be susceptible to informed and pluralistic public debate, including in the media.

Article 16 – Scientific and Rational Methods

Any decision or practice within the scope of this Declaration shall:

- (i) be made on the best available scientific information;
- (ii) pay due regard to any different information on the subject reasonably available to the decision-maker;
- (iii) be considered rigorously and in a principled manner;
- (iv) observe, when appropriate, proper procedures of risk assessment; and
- (v) be considered individually, allowing for the possibility of exceptions to general rules and practices.

Article 17 – Community and Expert Consultation

Any decision or practice within the scope of this Declaration, including those depending upon specialized scientific or other knowledge, shall take into account the need to reconsider regularly 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 18 – Fair Decision-Making Process

Any decision or practice within the scope of this Declaration, where differences arise, shall be resolved following full and free discussion and in accordance with fair procedures.

PROCEDURES

Article 19 – Risk Assessment

When there is scientific evidence of threats of serious or irreversible damage to public health and human welfare or the environment [biosphere], provisional adequate and proportionate measures shall be taken in a timely manner. Such measures shall be based on the best scientific knowledge available and carried out in accordance with the principles set out in this Declaration and with respect to human rights and fundamental freedoms.

Article 20 – Ethics Committees

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

- (i) to assess the ethical, legal and social issues related to scientific research projects and technological developments; and

- (ii) to devise guidelines and recommendations on issues within the scope of this Declaration, in accordance with the principles set out therein.

Article 21 – Ensuring Public Debate

States should ensure that citizens have an opportunity for informed, pluralistic public debate, ensuring the participation of all the stakeholders concerned and the relevant bioethics committee, and the expression of various sociocultural, religious and philosophical opinions.

Article 22 – Transnational Practices

[International research should be subjected to ethical review in the country providing financial support for the activity as well as in the country where the research is to be carried out. This review should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.]

[SPECIFIC ISSUES]

[.....]

PROMOTION AND IMPLEMENTATION

Article 23 – Bioethics Education, Training and Information

(a) In order to 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. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large.

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

Article 24 – Solidarity and International Cooperation

(a) States should respect and promote solidarity towards individuals, families, populations and groups, with special regard for those rendered vulnerable by health or other personal, societal or environmental conditions and those with the most limited resources.

(b) States should foster the international dissemination of scientific information and make every effort to guarantee the free flow and sharing of scientific and technological knowledge [namely throughout the creation of research and education structures in the developing countries as well as the transfer of technology].

(c) In the framework of international cooperation, States should promote cultural and scientific cooperation, endeavouring to enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge and of the related know-how.

Article 25 – 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 sphere of education, training and public information.

(b) States should establish a framework for the assessment and management of risks. This framework 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 26 – 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 therein. 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 will be addressed every two years to the International Bioethics Committee, which, after having examined them, will give its advice following the statutory procedures of UNESCO. After having examined the advice of IBC and the reports provided by States, the Intergovernmental Bioethics Committee will submit its opinion to the Director-General for transmission, together with the advice and recommendations of IBC, to the Member States, the Executive Board and the General Conference.

Article 27 – Follow-up Action by UNESCO

(a) UNESCO shall take appropriate action to follow up this Declaration so as to foster progress of the life sciences and their applications through technologies, based on respect for human dignity and the exercise and observance of human rights and fundamental freedoms.

(b) UNESCO shall reaffirm its commitment to dealing with all aspects of the biosphere and, if necessary, shall 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 the 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 therein, this Declaration could be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.

Article 28 – Interpretation

In their interpretation and application the principles set out in this Declaration are interrelated and each principle should be construed in the context of the other principles.

Article 29 – Restrictions

No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by 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 30 – Denial of Acts Contrary to Human Rights, Fundamental Freedoms
and Human Dignity**

Nothing in this Declaration may be interpreted as implying for any States, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.