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Committee (IBC)*

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de bioéthique (CIB)*

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**Fifth Meeting of the IBC Drafting Group
for the Elaboration of a Declaration
on Universal Norms on Bioethics**
UNESCO Headquarters (Paris), 27-28 October 2004

Final Report

Division of Ethics of Science and Technology

I. INTRODUCTION

1. With a view to further refining the text of a declaration on universal norms on bioethics, the Drafting Group of the International Bioethics Committee (IBC) held its fifth meeting at UNESCO Headquarters (Paris) on 27 and 28 October 2004 (List of participants in Annex I). The sixth meeting will be held in December 2004 as foreseen in the timetable for the elaboration of the declaration.

2. In accordance with the Agenda (Annex II), the Drafting Group devoted this meeting to the revision of those parts of the text that had not been covered during the fourth meeting (Paris, 25-27 August 2004), namely: Preamble, General Provisions (including a preliminary discussion on specific issues, particularly in relation as to what extent and in what way they should be dealt with in the future declaration), Promotion and Implementation.

3. The Group proceeded with this preliminary revision of the text of the declaration: it being understood that any modifications will have to be reconsidered later in the light of the results of the written consultation on the Third Outline of the future declaration (Ref. : SHS/EST/04/CIB-Gred-2/4 Rev. 2, dated 27 August 2004) carried out between October and December 2004 with Member States, intergovernmental and non-governmental organizations, national bioethics committees and a number of eminent personalities.

4. To facilitate the work of the Drafting Group, a working document had been prepared primarily taking into account the written comments received from members of IBC concerning the preamble and the sections entitled "General Provisions" and "Promotion and Implementation" of the Third Outline of the future declaration. Proposals received from other organizations, eminent personalities or Member States, as well as the discussions that took place during the eleventh session of IBC (Paris, 23-24 August 2004) were also examined.

II. PRESENTATION OF THE DISCUSSIONS ON THE ELABORATION OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS AT THE 170TH SESSION OF THE EXECUTIVE BOARD (PARIS, 8 OCTOBER 2004)

5. At the 170th session of the Executive Board of UNESCO (October 2004), the Director-General presented a report on the work carried out by UNESCO on the elaboration of a declaration on universal norms on bioethics. The aim of this report was to inform the Board of the progress made in the elaboration of the text which had led to the finalization of the Third Outline given in annex to the document presented (document 170 EX/9 and Addendum). In accordance with statutory procedures, the Executive Board also approved the invitations for the government experts meetings scheduled to be held in 2005.

6. Mr Henk ten Have, Secretary-General of IBC and Director of the Division of Ethics of Science and Technology, summarized the major lines of the debates concerning the declaration that took place during the Executive Board. The great majority of speakers recognized the important efforts made by IBC and its Drafting Group to achieve the Third Outline. They underlined the fact that the timetable set for the elaboration of the declaration, approved at the 169th session of the Executive Board, had been respected and that a large number of consultations had been carried out at all levels. They also applauded the transparency with which this work had been carried out. Some representatives indicated that national consultations on the text had been held within the framework of the "Ethics around the World" project. Speakers also expressed the wish for further consultations to be held, particularly with other intergovernmental organizations in order to avoid duplication and also stressed the involvement of the Intergovernmental Bioethics Committee (IGBC) in the elaboration process. Comments were made on the content of the text. Some felt for example

that the principle of responsibility of the human being with regard to the biosphere was an important innovation of the future declaration, whilst others insisted on the sharing of benefits or on education in bioethics. Some States - notably the Latin-American and Caribbean countries – expressed the wish that the declaration cover concrete subjects such as those set out in the Second Outline of the text.

7. Mr ten Have also informed the Drafting Group of the regional and national consultations on the future declaration that will be held over the next few months (Argentina, Indonesia, Mexico, Portugal, Republic of Korea, Russian Federation). The aim of these consultations is to associate national experts throughout the elaboration of the text in view of the government experts meetings.

III. DISCUSSION ON AN INTRODUCTORY PARAGRAPH AND REVISION OF THE PREAMBLE

8. Further to the discussions during the fourth meeting, the Drafting Group went on to examine an introductory paragraph that would allow the declaration to be put into context from the very beginning of the text. The aim of this paragraph would be to put forward the need for a global response to ethical issues raised by the rapid developments of science and technology – and thus justify the drawing up of a universal text; to bring out the responsibility of the human being to elaborate such a text given his/her unique capacity to express ethical principles to face the dangers that threaten not only his/her own existence but his/her environment, and to state clearly that it is time for the international community *stricto sensu* to state universal principles that will provide a foundation for humanity's response to these issues. The Drafting Group felt that this introduction should be an integral part of the preamble and constitute its opening preambular paragraphs.

9. The Group also examined proposed modifications that aim to recognize the role played in the field of bioethics by other intergovernmental organizations, in particular the World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO). Furthermore, although this does not conform with traditional wording for the preamble of a declaration, the Group wished to make explicit reference to certain texts drawn up by non-governmental organizations that have acquired a place of primary importance in the field of bioethics within the scientific community: in particular 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 et 2002) and the International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by the Council for International Organizations of Medical Sciences (CIOMS) (adopted in 1982 and amended in 1993 et 2002).

10. Furthermore, some members felt that it was important to draw particular attention to the family, to groups and communities in order to reflect the fundamental role they play and paramount importance given to them in some parts of the world and by certain cultural traditions. Modifications to this effect were accordingly made throughout the text.

11. Several members underlined the social responsibility that derives from bioethics and which demands that society deal with crucial issues to find solutions based on criteria of equity and justice. Examples such as access to health care, clean water, nutrition could be developed in the explanatory note.

IV. REVISION OF THE SECTION ON “GENERAL PROVISIONS” (INCLUDING A PRELIMINARY DISCUSSION ON SPECIFIC ISSUES AND TO WHAT EXTENT AND IN WHAT WAY THE FUTURE DECLARATION SHOULD DEAL WITH THEM)

12. The Group decided that it would be preferable to include definitions, if any, in a first article of the “General Provisions” section. At this stage, the Group concerned itself with formulating working definitions of the terms ‘bioethics’, ‘bioethics issues’ and ‘decisions and practices with bioethical implications’ for purposes of understanding and simplification of the text as a whole. These definitions would apply to the declaration and should in no way be considered as theoretical definitions. For the purposes of the declaration, bioethics would be defined as the systematic, pluralistic and interdisciplinary study of theoretical and practical moral issues raised by the life sciences and humanity’s relationship with the biosphere. Some members felt that it should be specified in the explanatory note that the life sciences should be understood in the broad sense of the term., i.e. encompassing medicine and the social impact of science and its applications.

13. With regard to the article concerning the scope of the declaration, the Group made some editorial modifications that aimed to clarify and simplify the formulations of the provisions contained in the text of the declaration.

14. The Drafting Group then discussed the ‘specific issues’ in order to reach a decision with regard to what extent and in what way the future declaration should deal with them. Bearing in mind the debates during the 170th session of the Executive Board, the Group nonetheless felt that in view of the timetable set it would not be possible to go into detail on all subjects and that the declaration would be situated on a more general level setting out major principles in bioethics. In any event, it would constitute the first universal text adopted by States together in the field of bioethics.

15. The Group felt that a general provision acknowledging the existence of specific issues that need to be examined could be added to the text and a list provided. It would be stipulated that these issues should be the subject of continued reflection and a future undertaking in accordance with Article 27 regarding the follow-up by UNESCO of the declaration. This provision should also recall that practices or decisions involving bioethical issues in specific areas should respect the principles set out in the declaration. Furthermore, whilst some members were in favour of the general provision as suggested, at the same time underlining the need for other international texts to be drawn up at a later stage, other members preferred that the declaration include one or two areas, such as research and health care. The Group decided to examine this question in further detail at its sixth meeting.

V. REVISION OF THE SECTION ON “PROMOTION AND IMPLEMENTATION”

16. The Drafting Group went on to examine article by article the section entitled ‘Promotion and Implementation’ and made some editorial changes to help clarify the text. With regard to the article concerning the role of States, some members felt that it was necessary to make reference to national bioethics committees, by asking States to encourage the setting up of independent, multidisciplinary and pluralist committees in accordance with Article 20 of the Third Outline of the text.

17. As for the Article concerning the role of IBC and IGBC, a number of different comments were made. First of all, members recognized that compared to the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, this provision was an innovation and a step forward in the implementation of a declaration. In fact, this Article provides for a reporting mechanism by

States in the implementation at national level of the declaration. Nevertheless, it appeared necessary to clarify the role of IBC and IGBC in relation to that of States. A new formulation would reposition the role of UNESCO by stating that reports by States should be submitted to the Director-General of UNESCO, who in turn would call upon the competence of the two committees.

18. The question of periodicity of the reports was also raised. The members were unanimously in favour of having a specific period indicated in the text in order to render this provision effective. It was decided that the reports should be sent every five years in order to ensure coordination with the time schedule of the General Conference of UNESCO.

VI. CONCLUSION

19. The working document as finalized after the fifth meeting is presented in Annex III. It will be the basis for the work of the Drafting Group at its sixth meeting but should not be considered as a revised version of the text of the future declaration. Changes proposed in the document will be further examined in the light of results of the written consultation on the Third Outline of the text.

20. In accordance with the timetable for the elaboration of the declaration, the sixth meeting of the Drafting Group will be held on 13 and 14 December 2004 in Paris. Furthermore, the fourth meeting of the United Nations Inter-Agency Committee on Bioethics which will be held on 10 December 2004, will focus mainly on the elaboration of the future declaration. On this occasion an exchange of views on the Third Outline with members of the Drafting Group will be organized within the ongoing consultation process initiated by UNESCO with other intergovernmental organizations.

**FIFTH MEETING OF THE IBC DRAFTING GROUP
FOR THE ELABORATION OF A DECLARATION
ON UNIVERSAL NORMS ON BIOETHICS**
(UNESCO Headquarters, Paris, 27 – 28 October 2004)

LIST OF PARTICIPANTS

Chairperson

Mr Michael Kirby (Australia)
Justice of the High Court of Australia
Member of the Ethics Committee, the Human Genome Organization (HUGO)
Former President of the Courts of Appeal of New South Wales and Solomon Islands
Former President of the International Commission of Jurists

Members

Mr Leonardo De Castro (Philippines)
Professor of Philosophy, University of the Philippines
National Coordinator of the Philippine Bioethics Network
Secretary of the International Association of Bioethics /
Vice-President of the Asian Bioethics Association
Member of the National Ethics Committee

Mr Gabriel d'Empaire (Venezuela)
Professor of Bioethics, Central University of Venezuela
Director of Coronary and Intensive Care Unit, Hospital de Clínicas Caracas
Director of the Bioethics Committee of the Venezuelan Cardiology Society
Guest Member of the National Academy of Medicine of Venezuela

Mr Alphonse Elungu (Democratic Republic of Congo)
Professor of Philosophy, University of Kinshasa
Chairperson of the Congolese Association of Philosophers
Member of the African and Madagascan Council for Higher Education
Consultant to the Agency for Cultural and Technical Cooperation

Mr Hans Galjaard (The Netherlands)
Emeritus Professor of Human Genetics
Former Head of the Department of Clinical Genetics, University Hospital Rotterdam

Mrs Yolanda Gómez Sánchez (Spain)
Professor of Constitution Law, *Universidad Nacional de Educación a Distancia*
Member of the Experts Committee, Bioethics Institute of the Foundation of Health Sciences

Mrs Nouzha Guessous-Idrissi (Morocco)
Professor and Head of Parasitology-Mycology Laboratory,
Faculty of Medicine and Pharmacy of Casablanca
Member of the Biomedical Research Ethics Committee,
Faculty of Medicine and Pharmacy of Casablanca
Founding Member of the Moroccan Organization of Human Rights

Mr Hector Gros Espiell (Uruguay)
Professor of International Law
Chairperson of the UNESCO Consultative Committee on the Teaching of Human Rights,
Culture of Peace, Tolerance and Democracy
Former Ambassador of Uruguay in France and to UNESCO
Former Minister of Foreign Affairs of Uruguay
Former President of the Inter-American Court of Human Rights

Mrs Michèle S. Jean (Canada), *Chairperson of IBC*

Adviser in programme development, Faculty of Higher Education, University of Montreal
Vice-President of the Administrative Council of the *Fonds de la recherche en santé du Québec*
Member of the Commission of Ethics of Science and Technology of Quebec
Member of the Permanent Ethics Committee of the Canadian Institutes of Health Research

Mr Adolfo Martínez-Palomo (Mexico)

Professor of Cellular Biology
Director General for Research, National Institutes of Health, Mexico
Coordinator of the Council of Science and Technology of the Presidency of Mexico
Member of the Third World Academy of Science
Former Director-General of the Centre for Research and Advanced Studies (CINVESTAV)
Former Chairperson of the Academy of Science of Mexico

Mr Takayuki Morisaki (Japan)

Professor of Molecular Pathophysiology, Osaka University
Director of the Department of Bioscience, National Cardiovascular Research Institute
Member of the Bioethics and Biosafety Commission, Council of Science
and Technology of Japan

Mr Edmund Pellegrino (United States of America)

Professor Emeritus of Medicine and Medical Ethics, Centre for Clinical Medical Ethics at
Georgetown University
Adjunct Professor of Philosophy, Georgetown University
Former Director of the Centre for the Advanced Study of Ethics
Founder of the Centre for Clinical Bioethics at Georgetown University

Judge Patrick Robinson (Jamaica)

Judge at the International Criminal Tribunal for the former Yugoslavia
Former Member of the United Nations International Law Commission
Former Deputy Solicitor-General, Jamaica
Former Chairperson of the Inter-American Commission on Human Rights

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**FIFTH MEETING OF
THE IBC DRAFTING GROUP
FOR THE ELABORATION OF A DECLARATION
ON UNIVERSAL NORMS ON BIOETHICS**

UNESCO Headquarters, Paris, 27-28 October 2004
Room XVI (Miollis Building)

Agenda

- Presentation of the discussions on the elaboration of a declaration on universal norms on bioethics at the 170th session of the Executive Board (Paris, 8 October 2004) by Mr Henk ten Have, Secretary-General of IBC
- Discussion on an introductory paragraph and revision of the Preamble
- Revision of the section on “General Provisions” (including a preliminary discussion on specific issues and to what extent and in and in what way the future declaration should deal with them)
- Revision of the section on “Promotion and Implementation”

The present document is the result of the deliberations of the IBC Drafting Group at its fifth meeting (Paris, 27-28 October 2004). It is a working document of the Drafting Group and in no way constitutes a revised version of the Third Outline (Ref.: SHS/EST/04/CIB-Gred-2/4 Rev. 2, dated 27 August 2004). Changes proposed in the document will have to be reconsidered by the Drafting Group at its sixth meeting, in particular in the light of results of the written consultation on the Third Outline carried out between October and December 2004.

DRAFT #7 REV.

Declaration on Universal Norms on Bioethics

or

**Universal Declaration on Bioethics
and [~~Humanity~~ / ~~Humankind~~ / Human Beings /
in relation to Human Beings / and Human Rights]**

The General Conference,

Reflecting on the rapid developments in science and technology, which increasingly touch the meaning of 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;

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;

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;

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 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 **Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993**, 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

The General Conference,

Reflecting on the rapid developments in science and technology, which increasingly touch the meaning of 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;

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;

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;

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 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

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 relevant international human rights 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).~~

~~Also recalling 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 the other international and regional instruments, national legislation and regulations in the field of bioethics and~~ Also recalling the international and regional codes of conduct and guidelines and other ~~ethical~~ texts in the field of ~~science and technology~~ **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 mutual respect of ~~men~~ human beings" 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 ethical values to guide scientific and technological development and social transformation, in order to ~~meet~~ identify emerging challenges in science and technology taking into account the responsibility of the present towards future generations, and that questions of bioethics, which necessarily have an international dimension, ~~raised by advances in science and technology,~~ should be treated as a whole, drawing on the principles already ~~affirmed~~ **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,~~

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),

~~Also recalling 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 that it is the mission of UNESCO to develop universal principles and norms 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 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,~~

Bearing in mind UNESCO's activities and programmes in the field of natural, social and human sciences, aiming at placing scientific and technological developments in a context of ethical **and societal** 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, **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 the bioethical issues may impact on individuals, families, groups or communities and humankind as a whole,

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

Also convinced that the social responsibility resulting from bioethics requires that the study and applications of bioethics take into account topical subjects of paramount interest, in order to help find solutions based on criteria of justice and equity.

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.

Bearing in mind UNESCO's activities and programmes in the field of natural, social and human sciences, aiming at placing scientific and technological developments in a context of ethical and societal 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, 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 the bioethical issues may 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,

Also convinced that the social responsibility resulting from bioethics requires that the study and applications of bioethics take into account topical subjects of paramount interest, in order to help find solutions based on criteria of justice and equity.

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.

<p style="text-align: center;">[Use of Terms]</p> <p style="text-align: center;">(Limited to scientific terms)</p>	
<p style="text-align: center;">General Provisions</p>	<p style="text-align: center;">General Provisions</p>
<p>Article 1 – Use of Terms</p> <p>For the purpose of this Declaration:</p> <ul style="list-style-type: none"><u>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study involving the theoretical and practical moral issues raised by the life sciences and humanity’s relationship with the biosphere;</u><u>(ii) the term “bioethical issues” refer to the theoretical and practical moral issues raised by the life sciences and humanity’s relationship with the biosphere as well as the availability and accessibility of scientific and technological developments and their applications;</u><u>(iii) the term “decision or practice” refer to a decision or practice arising within the scope of this Declaration involving bioethical issues.</u>	<p>Article 1 – Use of Terms</p> <p>For the purpose of this Declaration:</p> <ul style="list-style-type: none">(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study involving the theoretical and practical moral issues raised by the life sciences and humanity’s relationship with the biosphere;(ii) the term “bioethical issues” refer to the theoretical and practical moral issues raised by the life sciences and humanity’s relationship with the biosphere as well as the availability and accessibility of scientific and technological developments and their applications;(iii) the term “decision or practice” refer to a decision or practice arising within the scope of this Declaration involving bioethical issues.
<p>Article 4 2- Scope</p> <p>The principles set out in this Declaration:</p> <ul style="list-style-type: none">(i) apply to human beings <u>individuals, families, groups or communities [and humankind as a whole]</u>, while recognizing that human beings have responsibilities and duties <u>and responsibilities</u> towards other forms of life in the biosphere; and(ii) apply to <u>bioethical</u> issues raised by scientific and technological developments and their applications, as well as their availability and access;<u>(iii) apply to the related decision or practice.</u>	<p>Article 2- Scope</p> <p>The principles set out in this Declaration:</p> <ul style="list-style-type: none">(i) apply to individuals, families, groups or communities [and humankind as a whole], while recognizing that human beings have duties and responsibilities towards other forms of life in the biosphere;(ii) apply to bioethical issues;(iii) apply to the related decision or practice.

<p>Article 2 3 - Aims</p> <p>The aims of this Declaration are:</p> <ul style="list-style-type: none"> (i) 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; (ii) 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; (iii) to promote respect for biodiversity; (iv) to recognize the great benefit derived from scientific and technological developments, whilst ensuring that such developments occur occur 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; (v) 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; (vi) 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; (vii) to safeguard the interests of present and future generations. 	<p>Article 3 - Aims</p> <p>The aims of this Declaration are:</p> <ul style="list-style-type: none"> (i) 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; (ii) to ensure 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; (iii) to promote respect for biodiversity; (iv) to recognize the great benefit 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, and to prevent practices contrary to human dignity; (v) 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; (vi) 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; (vii) to safeguard the interests of present and future generations.
<p>General [Fundamental] Principles</p>	<p>General [Fundamental] Principles</p>
<p>Article 3 4 - Human Dignity, Human Rights and Justice</p> <p>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.</p>	<p>Article 4 - Human Dignity, Human Rights and Justice</p> <p>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 and for the universal principle of justice.</p>

<p>Article 4 5 - 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].</p> <p>Article 5 6 - 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.</p> <p>Article 6 7 - 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 <i>inter alia</i> to avoid discrimination and stigmatization of an individual, a family or a group].</p> <p>Article 7 8 - 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.</p>	<p>Article 5 - Beneficence and Non-Maleficence Any decision or practice shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice [to the persons concerned].</p> <p>Article 6 - Respect for Cultural Diversity and Pluralism Any decision or practice 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.</p> <p>Article 7 - Solidarity, Equity and Cooperation Any decision or practice shall respect the solidarity of humanity, ensure equity and encourage international cooperation [, in order <i>inter alia</i> to avoid discrimination and stigmatization of an individual, a family or a group].</p> <p>Article 8 - Responsibility towards the Biosphere Any decision or practice 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.</p>
<p style="text-align: center;">Derived Principles</p>	<p style="text-align: center;">Derived Principles</p>
<p>Article 8 9 - 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.</p>	<p>Article 9 - Primacy of the Human Person Any decision or practice shall be founded on the recognition of the primacy of the human person, which shall prevail over the [sole] interest of science or society.</p>

Article 9 10 - 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 11 - 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 12 - [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 13 - Privacy and Confidentiality

~~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 14- 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:

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In any decision or practice, 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.

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Article 14- 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:

<ul style="list-style-type: none"> (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. 	<ul style="list-style-type: none"> (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.
<p>Procedural Principles</p>	<p>Procedural Principles</p>
<p>Article 14 15 - Honesty and Integrity</p> <p>Any decision or practice within the scope of this Declaration shall:</p> <ul style="list-style-type: none"> (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. <p>Article 15 16- Transparency and Openness</p> <p>Any decision or practice within the scope of this Declaration shall:</p> <ul style="list-style-type: none"> (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. 	<p>Article 15 - Honesty and Integrity</p> <p>Any decision or practice shall:</p> <ul style="list-style-type: none"> (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. <p>Article 16 - Transparency and Openness</p> <p>Any decision or practice shall:</p> <ul style="list-style-type: none"> (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~~ 17 - 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~~ 18 - 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~~ 19 - 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~~ 20 - 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

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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~~ 21 - 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 ~~24~~ 22 - 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 socio-cultural, religious and philosophical opinions.

Article ~~22~~ 23 - 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.]

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[.....]

Promotion and Implementation

Article ~~23~~ 24 - 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~~ **and** 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~~ 25 - Solidarity and International Cooperation

~~b) a)~~ 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].

~~a) b)~~ 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 **and the benefits thereof**.

~~a) c)~~ States should respect and promote solidarity ~~towards~~ **between and among** individuals, families, ~~populations and~~ groups **and communities**, with special regard for those rendered vulnerable by ~~health~~ **diseases or disabilities** or other personal, societal or environmental conditions and those with the most limited resources.

Article ~~25~~ 26 - 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.

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Article 26 - 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.

b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees [, in accordance with Article 20].

~~b) c)~~ States should establish ~~a framework~~ **processes** for the assessment and management of risks. ~~This framework~~ **These 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 ~~26~~ 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, as appropriate, 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, will be addressed every ~~two~~ **five** years to the Director-General of UNESCO. ~~The International Bioethics Committee, which, after having examined [examining] 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~~ 28 - 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~~ **by evaluating new developments in science and technology and their applications according to the principles set out herein.**

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 and management of risks. These 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.

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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 all 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 year 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~~ 29 - 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~~ 30 - 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~~ 31 - 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.~~

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