



United Nations Educational, Scientific and Cultural Organisation
Organisation des Nations Unies pour l'éducation, la science et la culture



*International Bioethics
Committee (IBC)*

*Comité international
de bioéthique (CIB)*

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**Third meeting of the IBC Drafting Group
for the Elaboration of a Declaration
on Universal Norms on Bioethics**

UNESCO Headquarters (Paris), 2-3 July 2004

Final Report

Division of Ethics of Science and Technology

I. INTRODUCTION

1. The Drafting Group of the International Bioethics Committee (IBC), entrusted with the elaboration of a declaration on universal norms on bioethics, held its third meeting at UNESCO Headquarters, Paris, on 8 and 9 July 2004 (Agenda and List of Participants Annex I and II).

2. The Director-General of UNESCO, Mr Koïchiro Matsuura, delivered a speech at the opening of this third meeting which was followed by an exchange with the members of the Drafting Group. In his address (Annex III), the Director-General recognized the singular role of the IBC since its creation within the Organization, its expertise, its independence and the diversity of its representation, which fully justify the responsibility he had placed on the Committee in this new undertaking and the confidence accorded by Member States. He stressed the importance of transparent, concerted and multidisciplinary working methods to carry out successfully the elaboration of the future declaration and expressed his satisfaction that the results of the different consultations had been taken into account by the Committee. He also underlined the importance of keeping States regularly informed such as on the occasion of the Information Meeting of the Intergovernmental Bioethics Committee (IGBC) (Paris, 7 July 2004). The Director-General emphasized the main difficulty of the elaboration of such a declaration which is to conciliate the need to reach a common ethical framework of universal values with the pluralism derived from cultural diversity. In conclusion, he recalled the mandate of the General Conference which invites him to present a draft text to its 33rd session in 2005 and expressed his confidence that IBC would achieve its task of drafting a text in the given period of time.

3. Two concerns of the Drafting Group were then put before the Director-General. First of all, several members expressed the difficulty of the task conferred upon them given the sensitive nature of the subjects dealt with and the short time accorded to IBC which should not affect the quality nor the authority of the text produced by the Committee. They also felt that the consultations carried out contributed significantly to the efficiency of their work. Furthermore the Group wished to know to what extent the title of the declaration could be modified. The Director-General, recalling his obligation to respect the mandate of the General Conference and the timetable approved by the Executive Board at its 169th session, reiterated his entire confidence in the IBC to make every effort to draft a text of the highest quality possible in the time allowed and reminded the Group that the text of IBC would be further examined by government experts in 2005. The Director-General then reminded the participants that the terms of the Resolution of the General Conference must be respected but that, if IBC deemed it appropriate, recommendations to modify the title could be formulated. The final decision would nevertheless be made by the General Conference.

II. FINALIZATION OF A DRAFT DECLARATION FOR THE ELEVENTH SESSION OF IBC (PARIS, 23-24 AUGUST 2004)

4. In order to facilitate the work of the Drafting Group a working document had been prepared comprising, in a first part, the text drawn up by the Drafting Group at its second meeting (2-3 June 2004) and, in a second part, proposals for the text that had not yet been examined by the Drafting Group. The Drafting Group also took account of the comments and observations formulated during the Information Meeting of IGBC which took place at UNESCO Headquarters on 7 July 2004¹.

1. The report of the information meeting of IGBC is available upon request from the Division of Ethics of Science and Technology as well as on the Internet : www.unesco.org/bioethics.

Title

5. Further to comments made during the Information Meeting of IGBC concerning the use of the term “norms” and following the exchange with the Director-General, the Drafting Group decided to keep the title as it appears in the resolution of the General Conference, whilst proposing a second option in which the term “norms” would not be used and the word “universal” would be added to “declaration”. Given the extent of the field of application of the declaration and the universal value it encompasses, a more appropriate title seemed to be “universal declaration on bioethics”. The concept of norms in international law could be explicated in an explanatory note.

Preamble

6. The Drafting Group considered the possibility of shortening the preamble and to simplify the style, as suggested during the Information Meeting of IGBC. Some members considered the pedagogical value of the preamble which repositions the text in its historical and legal context; others wished to limit textual references to international instruments mainly drawn up by intergovernmental organizations. It was pointed out that current practice calls only for texts of United Nations bodies to appear in international declarations. The Group decided to maintain the present style of the preamble whilst diminishing the references to international texts adopted outside the United Nations system. Nevertheless, it felt that it was important to maintain the reference to the Oviedo Convention of the Council of Europe as well as a general reference to codes of conduct, guidelines and other texts of international and regional ethical scope in the field of science and technology that could be explicated in an explanatory note.

Definitions

7. Some members felt that it was necessary to define concepts such as bioethics in the actual text of the declaration stating clearly that they were “operational” definitions, i.e. without intending to provide absolute and rigid definitions but that they should apply only to the declaration. Notwithstanding, several members warned against the risk of trying to formulate an exact definition of bioethics which covers different notions according to cultural, philosophical and legal traditions. For the time being, the Group preferred to limit the definitions to scientific terms and, if need be, to clarify other concepts in an explanatory note.

Scope

8. The Group felt that there was redundancy with the rest of the text in the part dealing with scope. This part needed to be condensed and limited to the description of the field of application of the declaration, i.e. the human being, particularly with regard to issues raised by advances in science and technology and their applications. Some members also wished for it to be pointed out that bioethics also concerns access to and availability of such advances and their applications. In this regard, further to the consultations carried out, in particular with IGBC, the Group decided to maintain its position by focalising the declaration on the human being whilst recognizing his place in the biosphere.

9. The Group preferred to delete the reference to the human being “as an integral part of the biosphere” from the provisions concerning the scope, esteeming that the responsibilities and duties of the human being towards other forms of life derive from his/her attitudes and actions which affect the biosphere and not from the fact that he/she is a part thereof. Furthermore, considering that the provision concerning consensus, pluralism and cultural diversity constituted a general principle, the Group decided at this stage to delete the reference to it formulated under scope.

Aims

10. The Group reconsidered the order of the different provisions contained in the part devoted to aims. There was common agreement to affirm that the primary aim of the declaration was to provide a universal framework of principles and procedures aimed at guiding States in the formulation of their legislation and policies in the field of bioethics, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned. For some it also seemed redundant to affirm on one hand that the aim of the declaration was to ensure respect for human dignity and the protection of human rights and fundamental freedoms, and on the other hand to prevent practices contrary to human dignity, whilst for others there were two distinct aims. Finally, the prevention of practices contrary to human dignity had been added to the paragraph recognizing the positive aspects of science.

11. Discussion also took place on the promotion of respect for life in all its diversity, particularly respect for human life, the debate bearing not on the importance of respect for human life but on the way in which this principle could be reflected in the text of the declaration. Some participants insisted on making a special reference to human life because of its particularity since it is not just a right but the very basis of all rights, while others did not consider it necessary to make specific mention of it insofar as the right to life constitutes one of the fundamental rights of human rights. It was decided at this stage not to make mention in the text and to devote a paragraph to this in an explanatory note.

12. The Group felt that it would be opportune to provide in an explanatory note the distinction between the interests of present and future generations. Some members mentioned the fact that legally present generations have rights that are already covered by existing instruments (including the future declaration), whereas future generations have interests of which their protection deserves a special mention in the aims of the declaration.

General principles

13. In the light of observations formulated during the Information Meeting of IGBC and comments made by other members of IBC, the Group examined once again the general principles already established during the previous meeting.

14. The Group decided to reflect throughout the text the overriding importance of human dignity beginning in the part on general principles with the provision concerning human dignity, human rights and justice. Furthermore, in order to reinforce the notion of human dignity as a guiding thread throughout the declaration, some members wished that it be pointed out that the principles set forth in the declaration derive from human dignity which is inherent to the human being. Although several members were of the opinion that this reference would have more bearing if it figured in the part devoted to scope, it was finally decided to include it at the head of the general principles.

15. Discussion also took place on other principles that could be included in the general principles. In particular the principles of beneficence, autonomy, transparency, multidisciplinary and the precautionary principle were examined. The Group decided to include the principle of beneficence in order to reflect in the text the need to optimize the positive benefits of any decision or practice and to reduce the possible harms of such decisions or practices. As to the other principles, it was decided that they would be examined in the framework of the part concerning the application of the general principles and the procedural principles.

16. Concerning the article on diversity and tolerance, it was recalled that throughout the different consultations, in particular during the third meeting of the United Nations Inter-Agency Committee on Bioethics and the Information Meeting of IGBC, it was shown that the consideration of cultural diversity had been dealt with well in this paragraph. Some nevertheless wished that the duality of pluralism and the quest for universality be better reflected in this provision as in Article 5 of the Universal Declaration of UNESCO on Cultural Diversity (2001). It was decided to keep the present formulation and to add “cultural diversity” and “pluralism” to the title of the paragraph, and to refer to this duality and to the Declaration of 2001 in an explanatory note.

17. The Group felt that the phrase “any decision or practice in the field of bioethics” could lead to confusion and should be clarified in order to determine whether reference was being made solely to ethical reflection or also to decision and practices carried out at all levels in the field of science and technology. This phrase was thus replaced by “any decision or practice within the scope of this Declaration” in connection to the provisions on scope.

Application of the general principles and procedures

18. Discussion took place on the way in which the provisions should be included in the declaration avoiding any hierarchy of the principles set forth. The Group therefore decided to divide these provisions into three parts: the implications of the general principles that are a direct consequence of general principles, the applications of the general principles that would deal with concrete subjects and the procedural principles.

19. These parts will be the subject of more detailed discussion during the fourth meeting of the Drafting Group and members had been invited to forward written contributions for the text to the Secretariat.

Promotion and implementation

20. Members were reminded that the aim of this part was to ensure, at different levels, application of the declaration and of the principles set forth therein. It thus covers education and awareness raising, solidarity and international cooperation, a possible reporting mechanism as well as a system of evaluation and periodic revision, that would pave the way towards the development of the declaration and to the possible elaboration of other – even binding – texts.

21. The Group expressed its agreement on the provisions included in this part, it being understood that this part would be further discussed at the next meeting. A paragraph concerning the framework of the limitations to the application of the principles set forth in the declaration – as in Article 29 of the Universal Declaration on Human Rights (1948) – should be added. Particular attention will also need to be paid to the discussions that took place during the Information Meeting with IGBC, in particular some referred to the wish of IGBC that the creation of new follow-up mechanisms does not lead to a multiplication of subsidiary bodies of UNESCO.

Explanatory note

22. The Drafting Group considered that an explanatory note should be prepared to accompany the text of the declaration. It would allow the discussions that took place during the preparatory work for each part of the text to be reflected, to include textual references not included in the preamble, as well as concepts not defined in the text or of a certain ambiguity and to deal with specific issues to illustrate the application of the principles.

23. Members were invited to forward to the Secretariat suggestions for a text on the items they wished to be included in the note.

III. CONCLUSION

24. In the light of the exchange with the Director-General, the resolution of the General Conference, the state of progress of the work, the timetable of the consultations and the time available for drafting, in consultation with the Secretariat, the Drafting Group agreed to extend the fourth meeting of the Group, scheduled to take place immediately after the Eleventh Session of IBC (23-24 August 2004). It was also recalled that other members of IBC could be directly associated with the work of the Group during its fourth and subsequent meetings.

25. In conclusion, the Drafting Group, entrusted the Secretariat, in close consultation with Mrs Jean and Mr Kirby, with the revision of the first outline of the text of the declaration which, when finalized (in Annex IV), will be sent to all members of IBC in view of the eleventh session of IBC (Paris, 23-24 August 2004).

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

Paris, 8-9 July 2004
UNESCO Headquarters, Room VII (Fontenoy building)

Agenda

- Opening by the Director-General
- Introduction by Mr Michael Kirby, Chairperson of the Drafting Group, and presentation of the conclusions of the Information Meeting of the Intergovernmental Bioethics Committee (IGBC) on the progress of the work of drafting the future declaration (Paris, 7 July 2004)
- Presentation of the discussions on the first outline of a text of the declaration during the third meeting of the United Nations Inter-Agency Bioethics Committee (Paris, 24-25 June 2004) by Ms Michèle S. Jean, Chairperson of IBC
- Finalization of an outline of the declaration in view of the Eleventh Session of IBC (Paris, 23-24 August 2004)

**Third Meeting of the
Drafting Group of IBC**

LIST OF PARTICIPANTS

DRAFTING GROUP OF IBC

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 Hans Galjaard (The Netherlands)

Emeritus Professor of Human Genetics

Former Head of the Department of Clinical Genetics, University Hospital Rotterdam

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

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

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 Takayuki Morisaki (Japan)

Professor of Molecular Pathophysiology, Osaka University
Director of the Department of Bioscience, National Cardiovascular Research Institute

Mr Edmund Pellegrino (United States of America)

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

Mr Michel Revel (Israel)

Professor of Molecular Genetics, Weizmann Institute of Science
Israel Prize for Medicine (1999)

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

SECRETARIAT

Mr Henk ten Have

Secretary-General of IBC
Director
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Mrs Sabina Colombo

Programme Specialist
Bioethics Section
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Associate Expert
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Mrs Léonie Treguer

Documentation
Bioethics Section
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Ms Diana Body Lawson

Administration
Bioethics Section
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**Discours du
Directeur général de l'UNESCO,
M. Koïchiro Matsuura**

**à l'occasion de l'ouverture
de la troisième réunion du Groupe de rédaction du
Comité international de bioéthique (CIB)
Paris, le 8 juillet 2004**

Madame la Présidente du Comité international de bioéthique,
Monsieur le Président du Groupe de rédaction du CIB,
Mesdames et Messieurs les membres du CIB,

C'est avec grand plaisir que je me joins à vous aujourd'hui à l'occasion de la troisième réunion du Groupe de rédaction du CIB, chargé de mettre en forme la future déclaration relative à des normes universelles en matière de bioéthique.

Nous le savons, c'est notamment sur la base des études réalisées par le CIB que les Etats membres de l'UNESCO m'ont invité, en octobre 2003, à poursuivre l'élaboration d'une déclaration fixant un cadre éthique universel pour accompagner les progrès des sciences et des technologies.

Pour ma part, c'est tout naturellement que j'ai souhaité confier les premières étapes de la rédaction au CIB, qui a déjà joué un rôle majeur dans l'adoption de la Déclaration universelle sur le génome humain et les droits de l'homme en 1997 et de la Déclaration internationale sur les données génétiques humaines de 2003.

Par son expertise, son indépendance et sa diversité de représentation, le Comité joue aujourd'hui un rôle irremplaçable auprès de l'Organisation, qui justifie pleinement la responsabilité que j'ai voulu lui donner et la confiance que les Etats membres lui accordent.

Votre rôle est donc à présent d'envisager les structures et conditions d'un cadre éthique universel acceptable pour tous, pouvant également servir de base aux Etats désireux de se doter de législations et réglementations en la matière.

Pour mener ce travail à bien, vous pourrez vous inspirer librement des résultats et propositions issus des différentes consultations que j'ai souhaité engager parallèlement : celles-ci concernent notamment la consultation écrite auprès des Etats membres, la session extraordinaire du CIB qui a réuni de nombreux participants d'horizons variés en avril dernier, et la troisième réunion du Comité interinstitutions des Nations Unies sur la bioéthique qui a eu lieu il y a deux semaines à Paris.

Je reste convaincu, comme j'ai déjà eu l'occasion de le dire, que c'est par un tel engagement collectif, concerté et multidisciplinaire que nous saurons assurer le succès de l'élaboration de cette Déclaration. Je me réjouis ainsi d'avoir vu hier le Comité intergouvernemental de bioéthique (CIGB) être étroitement tenu informé de l'avancement de vos travaux et formuler des conclusions qui pourront ainsi également nourrir vos réflexions.

Enfin, je saisis cette opportunité pour vous dire combien il est important que les Etats membres soient tenus régulièrement informés des résultats de vos travaux, en toute transparence, et d'engager un débat aussi large et démocratique que possible avant de passer à l'étape des réunions intergouvernementales.

Madame la Présidente,

Le premier canevas de texte issu des deux premières réunions du Groupe de rédaction constitue déjà, je crois, une excellente base de travail pour la présente réunion.

Vous avez dû faire face à deux contraintes difficiles à concilier : la complexité de la tâche, reflétée par la grande variété des opinions exprimées, d'une part ; et un calendrier d'élaboration strict, d'autre part. Vous êtes cependant parvenus à trouver une issue en décidant de vous concentrer pour le moment sur l'être humain. Votre texte reflète la place qu'il occupe dans la biosphère et affirme sa responsabilité envers toutes les autres formes de vie.

Vous avez, dès le début de vos débats, insisté sur l'importance d'une référence au pluralisme, notion inhérente à celle de bioéthique qui reflète notre diversité culturelle. C'est une notion qui réside au cœur des missions de l'UNESCO en faveur du respect de la diversité culturelle – et qui se trouve en particulier soutenue par la Déclaration universelle de l'UNESCO sur la diversité culturelle adoptée en novembre 2001.

La future déclaration devrait concilier la nécessité de parvenir un cadre éthique commun de valeurs morales universelles et le pluralisme des points de vues qui doit être respecté. Le Comité international de bioéthique a toujours reconnu la nécessité du respect du pluralisme des points de vues, qui reflète la variété des traditions culturelles, politiques, historiques, religieuses et philosophiques. Le CIB a déjà adopté cette approche pluraliste quand il l'a estimé nécessaire, par exemple dans le Rapport sur l'utilisation des cellules souches embryonnaires dans la recherche thérapeutique (2001).

Mesdames et Messieurs,

Le mandat que m'a confié la Conférence générale de l'UNESCO s'inscrit dans un calendrier extrêmement serré puisque je devrai, à l'automne 2005, lui présenter un projet de déclaration à sa 33^e session.

Pour votre part, et comme prévu dans le calendrier de travail approuvé par le Conseil exécutif de l'UNESCO en avril dernier, votre tâche s'échelonne pour l'essentiel tout au long de l'année 2004. Vos travaux seront alors repris et poursuivis en 2005 par les experts gouvernementaux.

J'espère que les experts gouvernementaux démontreront l'année prochaine autant d'enthousiasme et d'esprit constructif que vous le faites aujourd'hui.

Pour ce qui me concerne, vous connaissez déjà mon attachement personnel aux questions de bioéthique et ma volonté de réussir, avec vous, cette entreprise qui répond à une attente très vive de la communauté internationale. Soyez donc assurés de mon soutien et de mon attention très scrupuleuse aux résultats et conclusions qui émaneront de vos travaux.

Je vous remercie donc à nouveau de votre disponibilité et vous souhaite deux jours d'intenses et fructueux échanges.



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*International Bioethics
Committee (IBC)*

*Comité international
de bioéthique (CIB)*

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Elaboration of the Declaration on Universal Norms on Bioethics : Second Outline of a Text

This second version of an outline of a declaration on universal norms on bioethics has been elaborated by the Drafting Group for consideration by the International Bioethics Committee (IBC) at its Eleventh Session (Paris, 23-24 August 2004).

It was revised following a preliminary review by the IBC Drafting Group at its third meeting (Paris, 8-9 July 2004), taking into consideration the observations formulated during the information meeting of the Intergovernmental Bioethics Committee (IGBC) (Paris, 7 July 2004) and the third meeting of the UN Interagency Committee on Bioethics (Paris, 24-25 June 2004).

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

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

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

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

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.

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, whilst 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

Human Dignity, Human Rights and Justice

Bearing in mind that the principles set out in this Declaration derive [are drawn / flow] from the inherent dignity of the human person and the duty to promote universal respect for, and observance of human rights and fundamental freedoms, any decision or practice within the scope of this Declaration [to which this Declaration applies] shall be made or carried out in the respect of the inherent dignity of the human person, and in accordance with the universal principles of justice, human rights and fundamental freedoms.

Responsibility for [towards] the Biosphere

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall have due regard for the impact on the interconnections of all life forms and the special responsibility of human beings for the protection of life in its diversity and of the biosphere within which human beings exist.

Beneficence

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall optimize the positive benefits and reduce the possible harms of such decision or practice.

Cultural Diversity, Pluralism and Tolerance

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall take into account the various schools of thought, value systems, historical and cultural backgrounds, and philosophical and religious traditions that make up our societies. However, cultural diversity shall not be invoked to infringe upon the principles set out in this Declaration, nor to limit their scope.

Solidarity, Equity and Cooperation

Any decision or practice within the scope of this Declaration [to which this Declaration applies] shall be guided by the solidarity of humanity, in order to avoid discrimination and stigmatization of an individual, a family or a group, to ensure equity and to encourage the sharing of scientific knowledge and cooperation.

Implication of the [Fundamental] General Principles

Primacy of the human person

Non-discrimination and non stigmatization

Autonomy

Consent

Confidentiality and Right to Information

Benefit sharing

Specific Issues

Scientific research

Research involving human subjects

Healthcare

Human Reproduction and the Beginning of Life

Reproductive human cloning

End of Life

Palliative care

Human and Organ Transplantation

Genetic and other Personal Healthcare Data

Germ-line interventions

Sex Selection

Pharmacogenetics

Non-commercialization of the human body and its parts

Generic drugs

Right to healthy food

Right to a healthy environment

Procedures [Procedural Principles]

Provision on procedures which should be followed at national and international level in science and technology, in particular:

- the need for democratic and transparent procedures,
- rationality and agreement,
- intellectual honesty and integrity of research,
- principles governing the dissemination of scientific knowledge,
- dialogue between specialists, policy-makers and society,
- the promotion and establishment of national bioethics committees and review boards at appropriate levels,
- the need for public consultations,
- the regulation of transnational practices

Promotion and Implementation

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.

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.

Role of States

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.

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.

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 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.

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.