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SCIENTIFIC AND CULTURAL ORGANIZATION**

EXECUTIVE BOARD

Hundred and seventy-second session

Item 3 of the provisional agenda

**REPORT BY THE DIRECTOR-GENERAL ON THE EXECUTION
OF THE PROGRAMME ADOPTED BY THE GENERAL CONFERENCE**

**Report of the Director-General on the drawing up
of a declaration on universal norms on bioethics**

SUMMARY

This document contains the final report of the second session of the intergovernmental meeting of experts aimed at finalizing a draft declaration on universal norms on bioethics, which took place at UNESCO Headquarters in Paris from 20 to 24 June 2005. It includes in annex the Universal Draft Declaration on Bioethics and Human Rights as approved by the intergovernmental meeting of experts on 24 June 2005.

**Second session of the Intergovernmental Meeting of Experts
aimed at finalizing a Draft Declaration on Universal Norms on Bioethics**

UNESCO Headquarters, 20-24 June 2005
(Room XI, Fontenoy building)

I. INTRODUCTION

1. In accordance with the timetable for the elaboration of the declaration, approved by the Executive Board at its 169th session (169 EX/Decision 3.6.2), and in application of 170 EX/Decision 3.5.1 of the Executive Board, the second session of the intergovernmental meeting of experts (category II) aimed at finalizing a draft of a declaration on universal norms on bioethics took place at UNESCO Headquarters in Paris from 20 to 24 June 2005.

2. As this second session was a continuation of the first session, the Agenda (SHS/EST/05/CONF.204/1) (Annex I)¹ and the Rules of Procedure (SHS/EST/05/CONF.204/2), adopted on 4 April 2005, applied *mutatis mutandis*. As indicated in the Agenda certain items had been concluded at the first session and others would have to be carried over to the second session of the meeting, taking into account the open-ended intersessional consultations between States. Furthermore, in accordance with the wishes expressed by government experts during the first session, interpretation and documents were available in English, French and also in Arabic Chinese, Russian and Spanish thanks to extra-budgetary resources, provided by Italy and Spain.

3. Governmental experts representing the following 90 Member States participated in the meeting with the right to vote: Albania, Algeria, Andorra, Argentina, Australia, Austria, Belarus, Belgium, Benin, Bolivia, Brazil, Burkina Faso, Canada, Chile, China (People's Republic of), Colombia, Costa Rica, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, Finland, France, Germany, Greece, Grenada, Guatemala, Haiti, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Ireland, Italy, Japan, Jordan, Kazakhstan, Kenya, Kuwait, Lebanon, Libyan Arab Jamahiriya, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Mauritania, Mexico, Monaco, Morocco, Niger, Norway, Oman, Peru, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Saint Vincent and the Grenadines, Saudi Arabia, Senegal, Serbia and Montenegro, Slovakia, South Africa, Spain, Sri Lanka, Switzerland, Syrian Arab Republic, Thailand, The Former Yugoslav Republic of Macedonia, The Netherlands, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, United Republic of Tanzania, United States of America, Uruguay, Venezuela and Vietnam. Palestine and the Holy See took part as observers, as did representatives of intergovernmental and non-governmental organizations. Mrs Michèle S. Jean, Chairperson of the International Bioethics Committee (IBC), attended the meeting as a resource person.²

4. The meeting was opened by the Director-General of UNESCO, Mr Koïchiro Matsuura, who, after thanking Mr Pablo Sader (Uruguay), Chairperson of the meeting, for his availability and the efforts he had made to carry out informal consultations between the two sessions, underlined the triple objective of the future declaration which should be a text of practical use: to guide States in the formulation of their legislation and policies, to provide a framework of principles and procedures for individuals, groups and institutions concerned in the field of bioethics and to foster dialogue within societies. The opening address of the Director-General is presented in Annex II.

¹ Annexes I, II, III et V are available on request from the Bioethics Section of the Division of Ethics of Science and Technology.

² The list of participants (SHS/EST/05/CONF.203/INF.3) is available upon request from the Bioethics Section of the Division of Ethics of Science and Technology and on the Internet (www.unesco.org/bioethics).

5. In his opening remarks, the Chairperson said that the task ahead was not an easy one, but, thanks to the spirit of cooperation during the informal consultations, this second session should permit constructive negotiations to be carried out and a clear and consensual text to be transmitted to the next session of the General Conference. The opening address of the Chairperson is presented in Annex III.

II. INTRODUCTORY STATEMENT BY THE SECRETARIAT CONCERNING THE OBJECTIVES OF THE MEETING AND THE WORKING DOCUMENTS

6. Concerning Item 6 of the Agenda, the Secretariat recalled the mandate of the meeting and presented the major lines of action taken within the framework of the follow-up to the first session in April. In accordance with the Recommendations adopted on that occasion, the Chairperson had transmitted the Recommendations to the Director-General and to the Chairman of the Executive Board. He also carried out a certain number of informal consultations in different forms. The Secretariat noted that on the basis of the Report by the Director-General on this matter, the Executive Board had defined the mandate of the second session in its Decision 16 considering that “the government experts, during the meeting of June 2005, should finalize and present a draft to the Director-General with a view to its transmission to the 33rd session of the General Conference of UNESCO in October 2005”.

7. In presenting the working documents of the session (Agenda, Rules of Procedure, Preliminary Draft Declaration on Universal Norms on Bioethics (SHS/EST/05/CONF.204/3), Explanatory Memorandum (SHS/EST/05/CONF.204/4) and the Compilation of Proposed Amendments (SHS/EST/05/CONF.204/5) submitted by Member States as of 6 June 2005), the Secretariat pointed out that the Compilation had been prepared as a reference document to facilitate the work and discussions of delegates. In no way was it intended to fix the position of each State. Contributions received after 6 June were distributed separately in their original language.

8. The Chairperson then referred to the informal consultations that he had carried out since the first session, in particular the informal meeting of 17 May, which had shown a favourable atmosphere for discussion and a willingness on the part of all States to debate in a constructive manner in order to achieve a positive result. Following this informal meeting, and on the basis of various exchanges and meetings held with delegations, the Chairperson identified a number of transversal issues that called for further reflection, presented in a ‘non-paper’ distributed to the delegates (Annex VI). As the general debate had already taken place during the first session in April, the Chairperson invited experts to make their interventions on specific items of the text without dwelling on general considerations.

III. DISCUSSION ON THE PRELIMINARY DRAFT OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS (PREAMBLE AND OPERATIVE PART)

9. The meeting proceeded with an article by article examination of the Preliminary Draft Declaration finalized by IBC. At the suggestion of the Chairperson, the discussions and drafting process were carried out in plenary and, when the need arose, informal groups were constituted in order to facilitate the work in plenary.

PRINCIPLES

10. With regard to the term “decision or practice” delegates reiterated the positions that had expressed during the first session and the informal consultations. Some delegates favoured its

deletion while others underlined the importance of keeping the notion of “practice” throughout the text. It was finally decided to include, at the beginning of the chapter devoted to principles, a heading that refers to decisions or practices taken or implemented by recipients in the field of application of the declaration and to reformulate the provisions in an impersonal manner by directly stating the principles.

Articles 1 and 2 – Scope

11. As during the informal consultations, there was a preference to merge Articles 1 and 2 into a single article focusing on the scope of the declaration and to define “to what” and “to whom” the declaration applies, thus avoiding entering into detail on a definition of bioethics which had been difficult to find consensus on. While they agreed unanimously that the declaration should focus on the protection of the human being, the delegates debated on how the article on scope should reflect the social aspect of bioethics and to what extent the field of application should extend to other fields such as social sciences. Furthermore, a wish was expressed for the inclusion of a reference to associated technologies related to medicine and the life sciences to be included. As far as the environmental aspect was concerned, certain delegates considered that the environment was a broader concept that did not require additional reference to the biosphere. While it was clear that the declaration was addressed to States, the article also referred to other actors concerned for whom the declaration should constitute a document of “inspiration” and guide their actions. On the basis of texts proposed by the representative of Germany and the delegate from Peru – seconded by delegations from the Andean community - Article 1 was drafted as it appears in the attached Draft Declaration.

Article 3 – Aims

12. As far as Article 3 is concerned, delegates wished that paragraph (i) reflect the distinction between the recipients, as made in the article on the scope of the declaration. It was thus decided to split this paragraph into two paragraphs, i.e. the first underlining the aims of the declaration with regard to States, and the second devoted to individuals, groups, communities, institutions and societies, whose actions the declaration would aim to guide.

13. During the first session of the meeting and in the informal consultations, some felt that it was important to refer to respect for human life in the same manner as respect for human dignity, whereas others, because of divergence in the definition of this notion in domestic law, expressed reservations. Others delegates felt that this notion was already included in the reference to human rights. Nevertheless, delegates recognized that this provision was central to a declaration on bioethics, and amendments were made to paragraph (ii) of the original text in order to ensure a reference to respect for the life of human beings. In this regard, while associating itself with the consensus, Japan wished to point out that it accepted the proposal on its understanding that the term “life of human beings” was employed in a general sense and meant life after birth. Moreover, Belgium reiterated its position concerning the expression “human being”, which should be prefer to “human person”.

14. Discussion also took place on freedom of research covered in paragraph (iii) of the original text. A balance was struck between the recognition of benefits deriving from advances in science and technology and the importance of ensuring that such progress be made in an ethical framework. While some delegates considered that it was important to make reference here to the social development that should underpin all research, it was preferred that this paragraph be devoted to freedom of research and to the benefits derived from advances in science and technology; the social aspect being reflected in other parts of the text.

15. Amendments were made to paragraph (iv) of the original text stipulating that the declaration aims to encourage multidisciplinary and pluralistic dialogue on bioethical issues. These amendments served to lighten the text by deleting the detailed enumeration of actors and, in this way, avoid the risk of giving an incomplete list. Nevertheless, it seemed important to keep the reference to society as a whole.

16. Paragraph (v) of the original text was considered a key provision for developing countries. It was suggested by some that issues concerning intellectual property raised in the field of medicine, the life sciences and by developments in new technologies, be dealt with here. However, considering that these issues also fall within the competence of other international organizations, it did not seem appropriate to deal with them in this declaration.

17. With regard to paragraph (vi) of the original text, for its final formulation it was suggested to draw on the Convention on Biological Diversity (1992) by referring to the conservation of biodiversity as a common concern of humanity.

18. Drafting and structural changes were made for a clearer understanding and coherency in the text.

Article 4 – Human Dignity and Human Rights

19. Discussions took place mainly on paragraph b) which deals with the question of the primacy of the human person; a balance needed to be found between the interest of the individual and the interest of society. While some preferred to delete the reference to society and to limit the formulation to science, others felt that the word “only” constituted balance in the formulation used. In the light of Article 30 on restrictions, Article 4 was adopted as it appears in the attached Draft Declaration.

Article 5 – Equality, Justice and Equity

20. Article 5 in its original content was unanimously accepted. Nevertheless, in considering that this Article sets forth a principle of paramount importance, particularly for developing countries, some delegates insisted on the necessity of avoiding differences in access to treatment in developed as well as developing countries. After the discussions of the informal group called for by the Chairperson and coordinated by the representative of Senegal, it was decided to maintain Article 5 in its original formulation, at the same time recognizing the desire of some delegations to make reference to double standards in another part of the declaration.

Article 6 – Benefit and Harm

21. With regard to Article 6, some delegates pointed out that the difficulty lay in the fact that this principle aims to set forth a general principle of benefit and harm in the field of application of the declaration, whereas its origin was exclusively in the field of medicine. Furthermore, in order to cover all situations – for example in the case of clinical testing – the notion of direct or indirect benefit to patients, research subjects and other individuals affected was introduced.

Article 7 – Respect for Cultural Diversity and Pluralism

22. All delegates acknowledged the importance of this provision, whose aim was to recognize the importance of cultural diversity and pluralism in bioethical reflection. Changes were made to lighten the text and to concentrate on the two concepts of cultural diversity and pluralism which were clearly defined within the framework of UNESCO.

Article 8 – Non-Discrimination and Non-Stigmatization

23. Article 8 did not appear to raise any major divergent points of view. The proposal made by certain delegates to include a reference to “unfair” discrimination was not retained since in international human rights law, the notion of discrimination covers situations of unfair treatment and since the text as drafted did not seem equivocal as to positive discrimination. Moreover, some delegates felt that it was important to place emphasis on those to whom this principle is addressed – the individual, families, groups and communities – who should be protected as well as both cases of stigmatization and discrimination. Others did not seem favourable to this proposal to the extent that the declaration cannot create a collective right that does not presently exist in international law. After the discussion of an informal group called by the Chairperson and coordinated by the representative of Brazil, the meeting approved the article as presented in the Draft Declaration attached.

Article 9 – Autonomy and Individual Responsibility

24. Article 9 did not seem to raise any fundamental differences. Changes in the original text were made mainly to clarify the fact that autonomy to make a decision should be respected but that the responsibility for this decision should be assumed in any event. Furthermore, some delegates underlined the importance of adding a phrase in this article for the protection of persons incapable to exercise their autonomy, while others were of the opinion that the case of incapable persons could be dealt with in the article on consent. After consultations coordinated by the representative of Portugal, the meeting agreed on Article 9 as reflected in the attached Draft Declaration.

Article 10 – Informed Consent

25. With regard to the article on consent, the delegates reiterated the positions expressed during the first session and the informal consultations. In particular, underlining the importance of consent in bioethics, which explains the central position given to this article in the declaration, some delegates wished for the provision concerning persons incapable of expressing their consent to be further developed. After the discussions of an informal group called by the Chairperson and coordinated by the representative of Italy, the meeting decided to approve the two articles on consent drafted by the informal group. The first article deals with the conditions required for consent, on one hand, with regard to preventive, diagnostic and therapeutic medical intervention and, on the other, with regard to scientific research. Paragraph c) addresses consent in the context of research carried out on a group of persons or a community. The second article is devoted entirely to persons incapable of giving consent. While associating itself with the consensus, the United Kingdom stated that it interpreted the “best interest of the person” as provided for in its domestic law. Some delegations stated that not sufficient time was devoted to this article. Canada expressed a reservations respecting the last sentence of article 6(b) because it was viewed as unnecessary in light of article 27 of the final draft declaration.

Article 11 – Privacy and Confidentiality

26. The debate concentrated on the question of exceptions to the protection of privacy and confidentiality, which are the subject of advanced legislation in a certain number of States in different fields. While some delegates therefore wished to make reference to national law, others felt that the aim of this provision was to ensure that these exceptions, which already exist in national law, be in conformity with international law. Moreover, the proposal made by a number of delegates to refer to information concerning health seemed too restrictive. On the basis of consultations coordinated by the representative of India, the meeting finally approved the formulation of a consensual text (as reflected in the attached Draft Declaration), on condition that a

new paragraph be added to the preamble, recognizing that the declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law.

Article 12 – Solidarity and Cooperation

27. Expressing its satisfaction with the spirit of this article, the meeting approved the original formulation with a few drafting changes. Some delegates wished to add a paragraph that would, on one hand, guarantee that transnational and international research aims to satisfy the needs of the host countries and, on the other, encourage transnational and international research to strive towards contributing to the resolution of global problems related to health. While recognizing the paramount importance of such a provision in the declaration, particularly for developing countries, it was decided to reconsider this question during the examination of Article 23 on transnational practices.

Article 13 – Social Responsibility

28. Numerous delegates, particularly representatives of developing countries, reiterated the paramount importance they placed on this article, which would allow for the social aspect of bioethics to be reflected. They wished that this provision also aim to specifically recognize a right to health and to affirm the promotion of health and social development as principles that should be applied by all, in particular by States. On the basis of a proposal presented by Brazil and Peru (seconded by Latin American countries and by other developing countries) and on the basis of amendments presented by the United States of America, the meeting reached a consensual text in a constructive spirit of compromise, particularly applauded by all delegates. Many delegates (including Belgium and Canada), while associating themselves with the consensus, nevertheless regretted that the reference to reproductive health no longer appeared in the approved formulation. In particular, Canada wished to point out that it would follow its traditional policy of supporting the inclusion of references to reproductive health in the appropriate forums.

Article 14 – Benefit-Sharing

29. It was recalled that Article 14 concerning benefit-sharing was drawn mainly from Article 19 of the International Declaration on Human Genetic Data and that it was an article of paramount importance in the declaration, particularly for developing countries. In its original formulation, Article 14 had not raised any particular difficulties. It was pointed out that the list of benefits included in the article was given simply as an example and was in no way exhaustive. Furthermore, paragraph b), which seemed to be redundant with the new preambular paragraph on domestic and international law, was deleted. Certain delegates underlined the need to make a warning here regarding possible inducement through benefits to take part in scientific research. After having examined the proposed amendments aiming to reinforce certain parts of the Article, the meeting approved the Article as it stands in the attached Draft Declaration.

Article 15 – Responsibility towards the Biosphere

30. With regard to the article on responsibility towards the biosphere, some delegates wished to add a reference to biological and genetic resources and to respect for traditional knowledge and practices. Given the disagreement of some delegates about the mention of traditional practices that could be contrary to human rights in certain cases, the representative of Burkina Faso wished to declare that within the framework of an instrument of the United Nations system, “traditional practices” could only mean practices in conformity with human rights. In addition, some delegates (among others Canada) pointed out that this article in its entirety should be interpreted in conformity with international obligations of States, including the Convention on Biological

Diversity (1992) and the provision in force concerning intellectual property rights, in particular the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPS).

New articles

31. On a proposal from Germany and Portugal, two new principles were added: one concerning the protection of future generations and the other related to respect for vulnerability; the latter in answer to those who wished for particular attention to be given to persons and groups in vulnerable situations.

CONDITIONS FOR IMPLEMENTATION

Articles 16, 17, 18, 19 and 21

32. On a proposal by Italy, it seemed preferable to regroup Articles 16, 17, 18, 19 and 21 of the original text, concerning respectively decision-making, honesty and integrity, transparency, periodic review and the promotion of public debate, into a single article entitled “Decision-Making and Addressing Bioethical Issues”.

Article 20 – Ethics Committees

33. Generally speaking Article 20 of the original text, modified according to some suggested amendments, seemed to cover the concerns expressed by States. In particular, certain delegates insisted that this article apply to all types of ethics committees (institutional committees, research committees, clinical ethics committees, etc.). Others wished to include an explicit reference to the role of advisory committees in the clinical context as well as in relation to scientific and technological developments. Emphasis was placed on the awareness and engagement of the public in the field of bioethics, which ethics committees should strive to promote.

Article 22 – Risk Assessment

34. Concerning Article 22, while some delegates felt that this provision does not come within the field of application of the declaration, others felt, on the contrary, that it was important to provide an ethical framework to assess and manage risks in the field of medicine, life sciences and associated technologies. Finally, the meeting decided to retain the article by amending it in such a way as to formulate a general principle without going into detail (as reflected in the attached Draft Declaration).

Article 23 – Transnational Practices

35. Article 23 was considered an important article that echoes bioethics issues raised by the increasingly international character of scientific research. Delegates approved the content of paragraphs a) and b) with some amendments aiming to render the text more comprehensible and coherent. The proposed amendment presented during the discussion on Article 12 to ensure that transnational and international research aim to satisfy the needs of host countries, and to encourage transnational and international research to strive to contribute to the resolution of global health problems, was approved as a new c). Furthermore, certain delegates wished for a reference to be made to the benefits of transnational research as well as to bioterrorism, illicit traffic in organs, tissues and samples, genetic resources and genetic-related materials, in two separate paragraphs.

IMPLEMENTATION AND PROMOTION OF THE DECLARATION

Articles 24, 25 and 26

36. Articles 24, 25 and 26 of the original text were approved with some changes. In Article 24 on the role of States, paragraph c), which was devoted to risk management, was deleted since an article was already devoted to this issue (article 22 of the original text). Furthermore, on a proposal of Italy, it was considered more appropriate to move the reference to young people to Article 25 on education, training and information in the field of bioethics. Article 26 dealing with international cooperation was also approved in its original formulation.

Articles 27 and 28

37. The discussion on Article 27 dwelt on two aspects. On one hand, with regard to the role of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) in the implementation of the declaration, some delegates felt that it was not appropriate to confer upon UNESCO advisory committees a role in the implementation of a declaration. Others delegates pointed out that similar provisions already existed in the International Declaration on Human Genetic Data and that in view of the contribution of these committees to UNESCO's action in the field of bioethics, it seemed important to make reference to the assistance that IBC and IGBC could lend UNESCO in the implementation and the follow-up of the declaration. The meeting thus decided to make reference to the two committees in Article 28 dealing with follow-up actions of UNESCO. Furthermore, delegates felt that it was inappropriate that a reporting mechanism be foreseen in such a declaration (originally formulated in Article 27), as well as a mechanism for periodic review of the declaration (originally formulated in Article 28 para.c)) and the possibility of drawing up other international instruments within the framework of UNESCO (originally formulated in Article 28 para. b).

APPLICATION OF THE PRINCIPLES OF THE DECLARATION

Article 29 – Interdependence and Complementarity of the Principles

38. The content of Article 29 of the original text was approved. Some changes were made to render the text more comprehensible, as it appears in the Draft Declaration attached.

Article 30 – Restrictions on the principles

39. With regard to restrictions on the principles, while some delegates wished for reference to be made to all those prescribed by law and which are consistent with international human rights law, others highlighted the importance of explicitly mentioning public safety, prevention of crime, protection of public health or protection of the rights and freedoms of others in order not to leave the door open to all sorts of restrictions. It was pointed out that this provision captured the spirit of Article 1 para. c) of the International Declaration on Human Genetic Data and it was proposed that the original formulation of this article be used. In addition, it seemed more appropriate to entitle the Article "Limitation to the Application of the Principles". The text as amended is presented in the Draft Declaration attached.

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

40. The meeting approved the original formulation of Article 31.

PREAMBLE

41. In general, delegates approved the spirit, structure and content of the preamble. Some editorial changes were suggested to lighten the text and to streamline the terminology used throughout the declaration. In addition, new references were included concerning, in particular, animals, health, indigenous and local communities, and identity of the person. After the discussion on Article 11 of the original text a new preambular paragraph was inserted, recognizing that the Declaration is to be understood in a manner consistent with domestic and international law, in accordance with human rights law. The meeting entrusted the Secretariat with finding the appropriate place in the preamble for this new preambular paragraph. The representative of Costa Rica, while associating itself with the consensus, expressed reservations as to the fact that the UN Declaration on Human Cloning adopted by the United Nations General Assembly on 8 March 2005 did not appear in the reference list of international instruments.

TITLE

42. The meeting decided to adopt the following title: “Universal Declaration on Bioethics and Human Rights”.

43. The meeting also wished to change the titles of certain sections: the section on “Conditions for Implementation” of the original text was modified as follows: “Application of the Principles” the section “Implementation and Promotion of the Declaration” of the original text was amended as follows : “Promotion of the Declaration”; and the section “Application of the Principles of the Declaration” was amended to read “Final Provisions”.

IV. ADOPTION OF THE REPORT AND CLOSURE OF THE MEETING

44. In concluding their work, the States represented at the second session of the intergovernmental meeting of experts adopted the Draft Universal Declaration on Bioethics and Human Rights (Annex IV) for presentation to the Director-General with a view to its transmission to the 33rd session of the General Conference in October 2005. It was pointed out that comments or statements on the Draft Declaration would be annexed to the final report of the meeting (see Annex V).

45. The participants adopted the report of the meeting, subject to changes to be made in accordance with suggested amendments that delegations were invited to address to the Secretariat in due course.

ANNEX

SHS/EST/05/CONF.204/3 REV
Paris, 24 June 2005
Original: English

**DRAFT UNIVERSAL DECLARATION
ON BIOETHICS AND HUMAN RIGHTS**

The General Conference,

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,

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

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

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

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,

Noting the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Recommendation of UNESCO on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPS) annexed to the Marrakech 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 noting 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, together with its additional protocols, 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,

Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law,

Recalling the Constitution of UNESCO adopted on 16 November 1945,

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

Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals,

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

Recognizing that health does not depend solely on scientific and technological research developments but also on psycho-social and cultural factors,

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

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

Also bearing in mind that a person's identity includes biological, psychological, social, cultural and spiritual dimensions,

Recognizing that unethical scientific and technological conduct has had particular impact on indigenous and local communities,

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

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity,

Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women,

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

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,

Proclaims the principles that follow and adopts the present Declaration.

GENERAL PROVISIONS

Article 1 – Scope

- (a) This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.
- (b) This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2 – Aims

The aims of this Declaration are:

- (i) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
- (ii) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;
- (iii) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;
- (iv) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need that such research and developments occur within the framework of ethical principles set out in

this Declaration and that they respect human dignity, human rights and fundamental freedoms;

- (v) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;
- (vi) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
- (vii) to safeguard and promote the interests of the present and future generations; and
- (viii) to underline the importance of biodiversity and its conservation as a common concern of humankind.

PRINCIPLES

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

Article 3 – Human Dignity and Human Rights

- (a) Human dignity, human rights and fundamental freedoms are to be fully respected.
- (b) The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and Harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and Individual Responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

- (a) Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
- (b) Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include the modalities for withdrawal of consent. The consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and

provisions set out in this Declaration, in particular in Article 27, and international human rights law.

- (c) In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

- (a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;
- (b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for Human Vulnerability and Personal Integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 – Privacy and Confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, Justice and Equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-Discrimination and Non-Stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 – Respect for Cultural Diversity and Pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13 – Solidarity and Cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 – Social Responsibility and Health

- (a) The promotion of health and social development for their people is a central purpose of governments, that all sectors of society share.
- (b) Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:
 - (i) access to quality health care and essential medicines, including especially for the health of women and children, because health is essential to life itself and must be considered as a social and human good;
 - (ii) access to adequate nutrition and water;
 - (iii) improvement of living conditions and the environment;
 - (iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and
 - (v) reduction of poverty and illiteracy.

Article 15 – Sharing of Benefits

- (a) Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
 - (i) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
 - (ii) access to quality health care;
 - (iii) provision of new diagnostic and therapeutic modalities or products stemming from research;
 - (iv) support for health services;
 - (v) access to scientific and technological knowledge;
 - (vi) capacity-building facilities for research purposes; and
 - (vii) other forms of benefit consistent with the principles set out in this Declaration.

- (b) Benefits should not constitute improper inducements to participate in research.

Article 16 – Protecting Future Generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 – Protection of the Environment, the Biosphere and Biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to the respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

APPLICATION OF THE PRINCIPLES

Article 18 – Decision-Making and Addressing Bioethical Issues

- (a) Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.
- (b) Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.
- (c) Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19 – Ethics Committees

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

- (i) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
- (ii) provide advice on ethical problems in clinical settings;
- (iii) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration; and
- (iv) foster debate, education, and public awareness of, and engagement in, bioethics.

Article 20 – Risk Assessment and Management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 – Transnational Practices

- (a) States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, which is undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.
- (b) When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.
- (c) Transnational health research should be responsive to the needs of host countries, and the importance of research to contribute to the alleviation of urgent global health problems should be recognized.
- (d) When negotiating a research agreement, terms for collaboration and agreement on benefits of research should be established with equal participation by those party to the negotiation.
- (e) States should take appropriate measures, both at the national and the international level, to combat bioterrorism, illicit traffic in organs, tissues and samples, genetic resources and genetic-related materials.

PROMOTION OF THE DECLARATION

Article 22 – 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, as set out in Article 19.

Article 23 – Bioethics Education, Training and Information

- (a) In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.
- (b) States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations in this endeavour.

Article 24 – International Cooperation

- (a) States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.

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

Article 25 – Follow-up action by UNESCO

- (a) UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).
- (b) UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

FINAL PROVISIONS

Article 26 – Interrelation and Complementarity of the Principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 – Limitations on the Application of the Principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

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