EXPLANATORY MEMORANDUM ON THE ELABORATION OF A DECLARATION ON UNIVERSAL NORMS ON BIOETHICS

(BASED ON THE FOURTH OUTLINE OF THE TEXT)

This document provides background information on the elaboration of the Fourth Outline of a declaration on universal norms on bioethics (Ref. SHS/EST/04/CIB-Gred-2/4 Rev. 3 of 15 December 2004) and presents the provisions contained therein. It aims at facilitating the debate and should not be considered as a document for the legal interpretation of the future declaration.

Division of Ethics of Science and Technology
I. Introduction

1. At the beginning of the twenty-first century, the increasingly complex interrelation between the different areas of medicine and the various life sciences is giving rise to a wide range of bioethical dilemmas.

2. As transnational cooperation in scientific activities intensifies, there is a growing need to develop universally applicable ethical guidelines in the field of bioethics. This involves the promotion of universally shared values and the organization of lively international debates between scientists, medical professionals, lawmakers and citizens.

3. The Constitution of UNESCO (adopted in November 1945) requires the Organization to “further universal respect for justice, for the rule of law and for human rights and fundamental freedoms”. In 1993, the Member States explicitly mandated UNESCO to work in the area of bioethics. UNESCO further reinforced the importance of this area of work through making ethics one of the five priorities of the Organization in 2002.

4. Over the years UNESCO has demonstrated its standard-setting role in bioethics. UNESCO has already contributed to the formulation of basic principles in bioethics through two major instruments: the Universal Declaration on the Human Genome and Human Rights, adopted unanimously and by acclamation by the General Conference in 1997 and endorsed by the United Nations General Assembly in 1998, and the International Declaration on Human Genetic Data, adopted unanimously and by acclamation by the General Conference on 16 October 2003.

5. In this context, at its 31st session in 2001, the General Conference invited the Director-General to submit a report on “the technical and legal studies undertaken regarding the possibility of elaborating universal norms on bioethics.” At the request of the Director-General, the International Bioethics Committee (IBC) therefore drafted the “Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics” finalized on 13 June 2003.

6. At its 32nd session in October 2003, the General Conference considered that it was “opportune and desirable to set universal standards in the field of bioethics with due regard for human dignity and human rights and freedoms, in the spirit of cultural pluralism inherent in bioethics” and invited “the Director-General to continue preparatory work on a declaration on universal norms on bioethics […] and to submit a draft declaration to it at its 33rd session” (32 C/Res. 24). The Director-General has thereupon entrusted the IBC with initiating the drafting procedure of the declaration.

7. At its 169th session in April 2004, the Executive Board of UNESCO approved the timetable for the elaboration of the future declaration. In accordance with the timetable, wide-ranging consultations were carried out from the very beginning and throughout the entire process of elaboration in order to involve the Member States, the United Nations, the other specialized agencies of the United Nations system, various intergovernmental organizations—in particular through the UN Inter-Agency Committee on Bioethics—, non-governmental organizations and appropriate national bodies and specialists.

II. Title

8. The title of the draft declaration, as mandated by the 32nd session of the General Conference is “declaration on universal norms on bioethics”.

9. The Drafting Group, however, proposes as a more appropriate title: “Universal Declaration on Bioethics and Human Rights”.

10. The title of the declaration has been addressed in regular and extraordinary sessions of the IBC, in meetings of the drafting group, as well as in consultations in the phase of the elaboration. During the consultations with Intergovernmental Organisations, Non Governmental Organisations, National Bioethics Committees as well as the written consultations with the Member States, it has been pointed out frequently that the adjective ‘universal’ before the term declaration would be more appropriate. It was also stressed by some responses that the term ‘principles’ would be more appropriate than the word ‘norms’. The word ‘universal’ refers not merely to the general applicability of the norms but also emphasizes the global recognition of bioethical principles. Every culture, even the most critical of technological advances, must develop a response - be it supportive or antagonistic - to the emergence of new technologies, including biotechnology.

11. The Drafting Group also stresses the importance of taking international human rights legislation as framework and starting point for the development of bioethical principles, as was the case with the Universal Declaration on the Human Genome and Human Rights. This could be emphasized by including Human Rights in the amended title.

III. PREAMBLE

12. The declaration on universal norms on bioethics necessarily requires references to international instruments and not only to the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data. In addition to the basic documents on human rights, international legal instruments that are not human rights documents per se might also have impacts on the domain of bioethics. For instance, Article 27(2) of the TRIPS Agreement of the World Trade Organization has an important influence on conceptualizing the patentability of the human genome.

13. Within the United Nations and among its specialized agencies, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) are mentioned as organizations that have adopted relevant instruments in the domain of bioethics.

14. Among many relevant instruments three especially important ones shall be singled out: (1) the Helsinki Declaration, (2) the Convention on Human Rights and Biomedicine of the Council of Europe, and (3) the International Ethical Guidelines for Biomedical Research Involving Human Subjects, prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the WHO, that is recognized worldwide, especially among scientists and policy makers. Reference to instruments adopted outside the United Nations system is new in the UNESCO legal tradition. In the area of bioethics the three mentioned instruments have special relevancy since they identify acknowledged principles and standards adopted at the international level.

GENERAL PROVISIONS

Article 1- Use of Terms

15. Article 1 provides three important definitions that are used throughout the text of the declaration. The first term is bioethics. In its short history, the term “bioethics” has had at least two different meanings, one broader than the other. The term was used for the first time by Potter (with a background in biology) in 1970. He advocated a comprehensive and global view of bioethics, as the moral analysis of the present and future of life. On the other hand, Hellegers (with a background in medicine) used the term “bioethics” for the first time in an
institutional way for an academic field of learning and a movement regarding public policy and the life sciences. Bioethics in this view is a new way of approaching and resolving moral conflicts generated by a new concept of medicine. This more restricted view has become dominant in the theory and practice of bioethics.

16. Having discussed this, and for the purpose of this declaration, the Drafting Group has adopted the following definition; bioethics is a systematic, pluralistic and interdisciplinary field of study involving the theoretical and practical moral issues raised by medicine and life sciences as applied to human beings and humanity’s relationship with the biosphere. This operational definition reflects the substantial changes that bioethics went through during its first appearance.

17. The second term “bioethical issues” refers to the theoretical and practical moral issues raised by medicine and the life sciences in four distinctive areas: application to human beings, humanity’s relationship with the biosphere, the availability and accessibility of scientific and technological developments and their applications. Life sciences are the sciences concerned with the study of living organisms. They encompass a broad range of disciplines that include, amongst others, biology, biochemistry, microbiology, virology and zoology. In recent years, many of these disciplines have increasingly focused on the characterization of the molecular events that define biological processes (often referred to as the “molecular life sciences”). Broadly speaking, life sciences include any study or research discipline that contributes to the understanding of life processes.

18. The third term in Article 1 is “decision or practice” that is within the scope of this declaration and involves bioethical issues. Principles of the declaration refer to this notion when the phrase ”any decision or practice” is used.

Article 2- Scope

19. Relevant for the interpretation of the notion “bioethics” is the difference between the subject and object of ethics.

20. The ‘subject’ of ethics (the moral agent) is necessarily a human being. This flows from the characteristics of ethics (rationality and normativity). Ethics is a quintessential human activity. Trees or cats do not have ethics. Human beings do not only develop ethical arguments but they are also the only entities that can act on the basis of such arguments. This does not imply that all human beings are moral agents (e. g. some lack rationality).

21. The ‘object’ of ethics (the moral patient) can extend beyond human beings. Ethical arguments can apply to entities that are unable to argue or to act on the basis of arguments, such as other species or the biosphere.

22. In the declaration, therefore, bioethical principles appeal to human beings; they address human beings as the moral agents.

23. However at the same time, depending on the definition of bioethics, there can be a difference in moral objects. Ethical principles can apply to different ‘objects’. In medical ethics the moral objects are a specific category of human beings: health care providers and health care recipients. In bioethics the moral objects can be all living beings, present life, and even future life.

24. The scope of this declaration appeals to human beings and it also covers their responsibility towards other forms of life in the biosphere such as animals and plants. However, the legal subjects recognized by the declaration are human beings.
25. During the elaboration of the declaration, especially on the grounds of the consultation with Member States, a list of topics was adopted to provide a manageable scope for the declaration. In present-day bioethics there are many topics (“specific issues”) that require (future) regulation. This list, however, only provides a summary of possible topics for inclusion in the declaration, based on the items listed in the Report on the Possibility of Elaborating a Universal Instrument on Bioethics, drafted by IBC in 2003.

26. However, many of the topics raised proved to be controversial and it was impossible to reach a consensus on them within the time frame given by the General Conference (such as for instance, moral issues regarding the beginning and the end of life). Several other topics were already addressed by other instruments, including the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data.

27. Consequently, the Drafting Group arrived at the conclusion that principles rather than rules or norms should be formulated, which would then provide a basis for developing specific legislation within the Member States and would also stimulate ethics teaching at local and regional levels. Formulation of principles will also guide future consensus regarding bioethical issues that are controversial today. If, in future, consensus emerges on such topics, they can be included in the scope of this declaration.

28. The aim of the declaration is not to conclude the debates on bioethics but rather to stimulate further ethics debates within the Member States in order to expand the Scope of this declaration. In the early stages of the development of bioethics it would have been impossible to reach consensus on almost any issue, whereas nowadays consensus is emerging in several areas and regarding several principles. Further consensus-formation can be expected in the future.

29. The above reasoning explains why Article 2 has two paragraphs. Paragraph a) articulates that the principles apply to human beings in various contexts as well as to bioethical issues and to any related decision or practice. The principles in the declaration therefore will take into account bioethical issues that may arise in future. Paragraph b) states that the principles apply to human beings but at the same time underlines that their responsibilities have a wider range.

**Article 3- Aims**

30. A universal instrument on bioethics must call for close attention to be paid to the importance of awareness raising: dissemination of information, education and consultation, as well as the promotion of public debate.

31. The declaration identifies eight major aims closely related to one another: it provides a universal framework of fundamental principles and basic procedures designed to guide States in the formulation of their legislation and policies in the field of bioethics. Furthermore, the declaration promotes respect for human dignity and the protection of human rights and fundamental freedoms; it recognizes the benefits derived from scientific and technological developments; it fosters dialogue. The declaration also aims to promote equality in scientific developments, to promote the greatest possible flow and sharing of knowledge concerning scientific and technological developments as well as benefits sharing, to recognize the importance of respect for biodiversity, and to safeguard and promote the interests of future generations.
Article 4- Interrelation and Complementarity

32. In the domain of bioethical questions consensus on specific issues will require balancing and weighing of principles. It is the nature of bioethics that several principles apply at the same time when confronted with a bioethical problem. If conflict occurs between principles, the assessment of the ethical dilemma should be based on carefully balancing the relevant principles, and on analyzing the arguments in order to determine which principle is overriding the other principles.

33. The principles identified in this declaration are therefore interrelated and complementary. There is not an a priori hierarchy of principles. Confronted with a specific bioethical problem, all relevant principles need to be taken into account in order to reach a reasoned conclusion about the ethical solution.

Article 5- Restrictions

34. Restrictions may be placed on the principles set out in the declaration only in accordance with international human rights law, if they are prescribed by domestic law; and only when it is necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others. In choosing between various restrictive measures, the principle of proportionality has to be respected because when restriction is necessary, rights derived from principles may be restricted only in the least restricted manner and proportional to the legitimate end of the restriction.

35. Since Article 5 formulates exceptions in restricted circumstances and for restricted goals, no exceptions are mentioned in the formulation of the principles themselves. Confronted with a specific bioethical problem, an ethically justified solution is usually only possible by balancing the principles. The solution is reached because one of the principles overrides other relevant principles. However, in exceptional circumstances formulated in this Article, the application of the principles set out in the declaration may be restricted. Even so, some limitations do apply since the restrictions should be consistent with international human rights law and should be prescribed by domestic law.

GENERAL PRINCIPLES

PRINCIPLES

36. Ethical principles always require further interpretation since the norms implicit in principles have to be translated into concrete rules.

37. Ancient ethical codes were often expressed in the form of an oath. One of the most well known, the Hippocratic oath, has already defined some principles that have become the basis of early ethics teaching worldwide. However, modern bioethics is indisputably grounded in the values enshrined in the Universal Declaration of Human Rights. Other texts of different legal force have established rules for the protection of persons in the wider field of biomedicine. The principle-based approach encompasses various schools of ethics, including the deontological as well as the utilitarian theories. Furthermore, the rule–principle distinction was elaborated not only in ethics but also in legal theory. Rules are applicable in an all-or-nothing fashion, while principles do not operate in this manner. Principles have a dimension that rules do not have, the dimension of weight and importance.
38. Despite their general nature, principles can serve as sources of legislation. Moreover, in comparison with concrete rules, principles would better accommodate rapid advances and changes in the biomedical sciences.

39. In the ethics vocabulary a ‘principle’ is a normative generalization that serves as a justification for particular prescriptions and evaluations of human actions. The notion of principle combines two meanings:

- **principium**: the starting point, beginning of an argument; in reasoning one has to start somewhere; a principle is the point of departure of a time of argumentation;
- **princeps**: the most important consideration, overriding other arguments or notions.

40. In the previous drafts of the declaration a distinction was made between fundamental and derived principles. In the draft text, a second category of principles was identified, labelled as ‘derived principles’. This reflects the situation in bioethics itself where in daily practice one often works with ‘intermediary principles’. In the phase of revising the previous drafts and taking into account comments provided to the Drafting Group the distinction was later eliminated in order to eliminate any suggestion of a hierarchy among the principles.

41. Without providing a hierarchy among the guiding principles during the elaboration of the declaration, a distinction was made between ‘general principles’ and ‘implementation principles’.

42. Furthermore, the declaration made a distinction between the principles directly related to respect for human dignity such as respect for human rights and fundamental freedoms, beneficence and non-maleficence, autonomy, consent and confidentiality; the principles concerning the relationships between human beings such as solidarity, cooperation, equity, justice, cultural diversity; and the principles governing the relationship between human beings and other forms of life and the biosphere such as the responsibility towards the biosphere and the assessment of risks.

43. The order of the principles in the declaration therefore follows a particular rationale or systematic approach.

44. These principles represent different rational justifications for human actions. None of them provide an overriding justification. This is a major characteristic of ethics. If there were one fundamental principle, ethics would be quite simple because all human actions could be justified in terms of one principle only. What makes ethics complicated is that several principles apply and that one has to balance and weigh arguments continuously in order to determine the best course of action.

45. The rationale followed in the draft declaration is to present the general principles in the following way: they determine the different obligations and responsibilities of the moral agent in relation to different categories of moral objects, gradually widening the range of moral objects, as follows:

- **Human dignity**: the moral object is the individual human being itself
- **Beneficence**: the moral object is another human being
- **Respect for cultural diversity**: the moral object is human communities
- **Solidarity and co-operation**: the moral object is humankind as a whole
- **Responsibility towards the biosphere**: the moral object is all living beings and their environment.
Article 6- Human Dignity and Human Rights

46. In the declaration human dignity is recognized as a core principle upon which other principles rest. Respect for human dignity flows from the recognition that all persons have unconditional worth, each having the capacity to determine his or her own moral destiny. Disrespecting human dignity could lead to the instrumentalization of the human person.

47. Another feature of human dignity is emphasized in Article 6 b) which states that interest and welfare of the human person prevail over the sole interest of science or society. Primacy of the human person has been expressed in various international documents, 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. The Convention states in its Article 2: “The interests and welfare of the human being shall prevail over the sole interest of society or science.” Of course, this principle should be balanced with other principles, such as the principle of solidarity and justice.

48. Respect for human dignity has been cited frequently in various biomedical and legal contexts. The concept is frequently used in the Universal Declaration on the Human Genome and Human Rights.

49. There are many different views on the relation between human rights and bioethics. Though they are different disciplines, declarations and documents on bioethics should be in harmony with the universal norms of human rights.

Article 7- Equality, Justice and Equity

50. Article 7 deals with three notions closely connected with one another. ‘Equality’ refers to the equal treatment of individuals in a similar situation while the term ‘equity’ refers to discretion, which serves as a corrective mechanism to formal equality by looking at the special circumstances. ‘Justice’ in the philosophical sense is a normative principle that refers to a judgement on the arrangement of institutions, society, groups of individuals, etc. A commonly definition of justice would be: treating equals equally, unequal unequally.

51. Principles of justice are essential to the structure of a constitutional democracy. Fairness and due process are part of democratic legal systems and are closely related to the foundations of human rights. In addition to the general meaning, principles of justice play an important role in many decisions and practice in the field of bioethical issues, such as in allocating health care services and setting priorities in health care.

Article 8- Beneficence and Non-Maleficence

52. Although the principles of beneficence and non-maleficence are sometimes stated separately, the two principles originating from the ancient maxim of ‘do good’ and ‘do no harm’ (primum non nocere) seem to be effectively treated in one single Article as the ethical imperative represents two aspects of the same claim.

Article 9- Respect for Cultural Diversity and Pluralism

53. Cultural diversity refers to the manifold ways in which the cultures of social groups and societies find expression. From the diverse forms taken by culture over time and space stem the uniqueness and plurality of the identities and cultural expressions of the peoples and societies that make up humankind.
54. Respect for cultural diversity requires careful implementation. If ethical standards are dictated and simply copied in various legal systems without adequate interpretation, they may remain as mere legal transplants that will not function properly with other elements of bioethical norms in a given country. Therefore the existence of cultural diversity, the importance of cross-cultural perspectives and the principle of pluralism are recognized by the declaration.

55. According to the Universal Declaration on Cultural Diversity, diversity reflects the uniqueness and plurality of the identities of the groups and societies making up humankind. As a source of exchange, innovation and creativity, cultural diversity is as necessary for humankind as biodiversity is for nature.

56. However, the principle of respect for cultural diversity can easily be used to override any other moral consideration. It is therefore added (as in the UNESCO Universal Declaration of Cultural Diversity) that this principle cannot be used to limit the application of the other universal principles.

Article 10- Non-Discrimination and Non-Stigmatization

57. Article 10 of the declaration does not deal with all forms of legitimate distinctions between people. It focuses only on unlawful, unfair discrimination between people based on any grounds.

58. The prohibition of discrimination has been elaborated in various legal instruments and one of the most eloquent and pioneer statements can be found in Article 6 of the Universal Declaration on the Human Genome and Human Rights. This article introduced a new ground of discrimination and stimulated similar legal instruments worldwide to prohibit discrimination based on genetic characteristics.

59. Discrimination, both in its direct and indirect forms treats a morally neutral and immutable characteristic (such as skin colour, gender, genetic characteristics) as having a negative impact and, based on that illegitimate distinction, similarly situated individuals are treated differently. In addition to various forms of discrimination, stigmatization is also prohibited by the declaration.

60. The history of medical research shows a disturbing pattern of discrimination against different groups: ‘races’, ethnic minorities, and women - even in the recent past. During the conceptualization of research and the establishment of control groups, culturally, morally or legally problematic categories may be used, and the preemption of discriminative practices requires communication between the various disciplines.

61. The elimination of discrimination has to be ensured in the different areas of health care, biomedical research and health policy formulation. Not only direct forms of discrimination, such as that which appeared in the often-cited Tuskegee Study, but also the various indirect forms should be eliminated.

62. Discrimination may distort scientific progress. For instance, the routine exclusion of women from research trials led to the fact that many of the conditions specific to women remained unknown and that discoveries that were applicable to men were simply assumed to be applicable for women patients.

63. Stigmatization often lingers even after the discriminatory laws and policies are abolished but it may also occur before discrimination is manifested in more direct forms. While prohibition of discrimination can be more easily targeted by legal instruments, elimination of the stigma requires a longer process of social transformation in which ethics and ethics teaching can play a predominant role.
Article 11- Autonomy and Individual Responsibility

64. Respect for personal autonomy is strongly linked to and derives from the notion of human dignity. Individuals cannot be instrumentalized and treated as means or goals; they should be granted the authority to make autonomous decisions in all aspects of their lives without doing harm to others. Respect for autonomy is not just a respectful attitude but it involves respectful action. However, autonomy, in this interpretation, is not simply an invested right but also has the dimension of responsibility towards others. Article 10 reflects the right of each person to make individual decisions, whilst at one and the same time respecting the autonomy of others.

Article 12- Informed Consent

65. Informed consent is a fundamental element of contemporary bioethics. The right of individual self-determination has been the basis for court decisions in favour of informed consent of competent patients to health care procedures. Though the doctrine of informed consent is largely a creation of court decisions, it rests ultimately on moral foundations.

66. Article 12 deals with this concept in two major domains. Paragraph a) deals with informed consent in the field of scientific research; paragraph b) refers to any decision or practice with regard to medical diagnosis and treatment.

67. Paragraph a) requires prior, free, informed and express consent of the persons concerned. This consent may be withdrawn at any time and for any reason.

68. According to paragraph b) regarding decision or practice related to medical diagnosis and treatment the person concerned must receive appropriate information about the decision; must fully participate and must consent. Although the requirement of express consent for diagnosis and treatment is under normal circumstances too stringent, as a general rule—as is the case in other international and various national legal instruments - an affected individual has to receive relevant, structured and individually tailored information that makes him or her able to make a decision on whether or not to accept medical treatment, as well as to understand and cope with the diagnosis.

69. Paragraph c) differentiates between research that provides direct health benefit to a person who does not have the capacity to consent and research that does not provide direct health benefit to the person concerned. In this latter case, research may be undertaken only as an exception with the utmost restraint and in a manner that exposes the person to only minimal risk and minimal burden.

70. Paragraph d) states that, when in accordance with domestic law, a person is incapable of giving informed consent (for instance in case of mental incapacity) authorization for medical diagnosis and treatment should be obtained in accordance with domestic law in the best interest of the person concerned.

Article 13- Privacy and Confidentiality

71. Right to privacy guarantees a control over personal information in many ways. It restricts access to personal and medical information and it provides a claim of non-interference in various private spheres of the individual. Privacy extends beyond data protection, as certain private spheres of the individual that are not manifested in data processing can also be protected by the right to privacy. Confidentiality refers to a special fiduciary relationship, such as between researcher and research subject, or doctor and patient, and provides that the shared information shall remain secret, confidential and shall not be disclosed to third persons, unless a strictly defined compelling interest justifies disclosure under domestic law.
Article 14- Solidarity and Cooperation

72. The declaration is based not only on the individualist concept of rights but also recognizes the importance of solidarity between individuals and across communities.

73. Inequalities in access to health care worldwide increase the importance of including solidarity and equity among the basic principles. The idea of collective social protection and fair opportunity should be a governing principle in policy decisions and it is an essential element of a population-based ethics. Furthermore, in the planning of health care systems special attention should be paid to vulnerable groups, such as to women, by providing access to reproductive health services and to children in guaranteeing their access to health care.

Article 15- Social Responsibility

74. The Preamble of the declaration expressed the need for a new approach to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity and to the interest of humanity.

75. Article 15 was included in the declaration in order to reflect a new agenda for bioethics, taking into account a wider social dimension of scientific progress. Five specific elements were singled out: access to quality health care, including sexual and reproductive health, access to adequate nutrition and water; reduction of poverty and illiteracy, improvement of living conditions and the environment, and the elimination of the marginalization and exclusion of persons on the basis of any ground, including gender, age or disability.

76. Elimination of the marginalization and exclusion of persons on the basis of any ground, including gender, age and disability was recognized as different than elimination of discrimination as stated in Article 10. Marginalization may be a result of discrimination, although not necessarily. Marginalization of a group of individuals may have disadvantageous consequences in the field of health, such as insufficient access to information, to health services and to benefits of scientific development.

Article 16- Sharing of Benefits

77. Sharing of benefits often appears in various legal documents on genetic resources. In its Article 1, the UN Convention on Biological Diversity emphasizes “fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.” Furthermore, Article 12(a) of the Universal Declaration on the Human Genome and Human Rights states that “benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.” The International Declaration on Human Genetic Data devotes a special Article, Article 19, to the sharing of benefits and provides a useful tool for identifying various forms of benefits.

78. The present declaration goes far beyond the scope of genetics including the sharing of benefits resulting from scientific research in general, using almost identical formulations to those used in the Declaration on the Human Genome and Human Rights.
Article 17 - Responsibility towards the Biosphere

79. The Preamble of the declaration reflects the need that was also expressed during the public consultations that a contemporary declaration on bioethics should extend its scope beyond human beings. The Preamble refers to the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997. Moreover the Preamble recognizes that human beings are an integral part of the biosphere and that they have responsibilities and duties towards other forms of life. Although the principles set out in this declaration apply to human beings, it is articulated in this article that they have responsibilities towards other forms of life in the biosphere.

80. The concept of human relations with the biosphere recently underwent substantial changes by the recognition of interdependence between humans and their environment. Parallel to this recognition, the norms governing this field have been altered significantly. The preventive attitude in standard setting is more recent and therefore the public support for these preventive legal standards is not evident as the standards often require change of the already existing preferences in lifestyle and in social and economic policy decisions. In order to promote such changes, the declaration includes this principle among the fundamental principles of bioethics.

81. With regard to responsibility towards the biosphere, a special reference to future generations is made in the text to the safeguarding of interests in biodiversity and the biosphere that extend beyond the present generation.

IMPLEMENTATION PRINCIPLES

82. Implementation principles describe the procedural rules of decision-making that have to be followed and the framework to put into place for the application of the principles, particularly in the case where a balance needs to be found between the applications of several principles that seem relevant at the same time. In earlier drafts the term 'procedural principles' was applied but the Drafting Group felt that the word procedural has strong judicial connotations and therefore applied the term 'implementation'.

83. In contrast with substantive principles in Articles 6-17 that provide guidance for the content, implementation principles are not thematic and do not deal with the content of ethics decisions, but rather refer to the fairness of the process leading to ethically acceptable decisions in various fields of bioethics.

84. The declaration identifies five principles: honesty and integrity, transparency and openness, fair decision-making, scientific and rational methods, and periodic review.

Article 18 - Honesty and Integrity

85. Article 18 prescribes four elements of decision-making and practice within the scope of the declaration: professional independence, intellectual honesty, respect and need for integrity in scientific and other research, problems resulting from a conflict of interest, and sharing of information with the public.

86. Conflict of interest refers to a clash between the public interest and the private (often pecuniary) interest of the individual concerned. It is usually interpreted in the context where public officials and fiduciaries have a special relationship to a specific matter. Conflict may occur between public, academic and business interests, or between medical, scientific and economic interests.
Article 19- Transparency and Openness

87. Interpretation of scientific discoveries has many pitfalls. Ethical analyses are not necessarily based on an accurate assessment of scientific developments, and these interpretations sometimes misread the effects of applying new biotechnologies. Moreover, normative interpretations may also be distorted due to factors that are entirely independent of scientific research. The complex issues in the contemporary life sciences and biotechnology have to be addressed within a broader cultural and social context. Trust in science can be enhanced by making science more transparent and accessible to the public.

Article 20- Fair Decision-Making

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

89. When a decision has to be made about an issue that is within the scope of the declaration, a fair, unbiased procedure - where different positions are taken into account within a reasonable time - shall be initiated. Article 20 of the declaration prescribes that any decision or practice within the scope of the declaration shall be resolved following full and free discussion and in accordance with fair procedures and shall be determined with particular regard to the circumstances of the persons concerned.

Article 21- Scientific and Rational Requirements

90. History provides numerous examples of the fact that unethical scientific research is also bad scientific research. Similarly, failure to comply with the scientific method in research may easily result in unethical consequences for research participants, scientists and society in general.

91. The declaration identified five main criteria for achieving the goals of this principle: the decision and practice should be based on the best available scientific evidence; due regard should be payed to different information available. They should also consider rigorously and in a principled manner, appropriate procedures of risk assessment, and individually tailored decision-making.

Article 22- Periodic Review

92. In the field of bioethics, standard-setting and political decision-making require interdisciplinary consultations and the widest possible involvement of the public.

93. Although Article 12 of the declaration already underlines the importance of individual consent, there are fields of research in which the acquisition of individual consent and the safeguarding of public involvement are not satisfactory. As biobanks are created in many developed countries, entire national populations are susceptible to becoming subjects of genetic research. On the other hand, the exploitation of genetic material from less developed countries requires the development of ethical guarantees.

94. Therefore, Article 22 prescribes the need to reconsider regularly the state of specialized scientific or other knowledge and the need to engage in a regular dialogue with the society.
The declaration distinguishes four target groups with whom regular dialogue should be maintained: persons affected by these decisions or practices, members of relevant disciplines, appropriate bodies, and civil society.

PROCEDURES

Article 23- Risk Assessment

Article 23 states the procedures to be followed when there are new scientific and technological developments, possibly leading to serious or irreversible damage to public health and human welfare or to the environment, and when at the same time, scientific evidence for such damage is insufficient.

In such situations of uncertainty, timely measures shall be taken to assess the risks involved. The assessment procedures should evaluate the ethical issues at stake. The outcome of the assessment can vary from accepting the development, regulating and monitoring the development, accepting a moratorium, or prohibiting the development.

The measures taken under Article 23 shall be based on the best scientific knowledge available and carried out in accordance with the principles set out in the declaration and with respect to human rights and fundamental freedoms.

Article 24- Ethics and Bioethics Committees

The term ‘ethics committee’ is used in a broad sense as it embraces policy-making committees, quality assurance committees, peer-review committees, utilization review and risk management committees, scientific-review committees, and even intra-institutional committees. This reflects a current trend in which bioethics committees are beginning to accept a broader mandate, covering not only the ethical issues related to medicine and the life sciences, but also the ethical issues generated through the advances of science and technology in general. The declaration intends to reinforce the role of various ethics committees in the fields within the scope of the declaration, including the domain of research ethics and furthermore to strengthen the role of ethics committees in interpretation of the principles of bioethics. In this respect ethics and bioethics committees have an essential role in the implementation of the declaration.

The need for independent, multidisciplinary and pluralist committees has already been stated in many documents. The declaration emphasizes the importance of these criteria for assessment the ethical, legal and social issues related to scientific research projects and technological development and for the development guidelines and recommendations, in accordance with the principles set out in the declaration.

Article 25- Ensuring Public Debate

This obligation is imposed on Member States and not just on ethics and bioethics committees. As Articles 18 to 24 logistically follow the procedures for making a decision on ethical issues, in public debate the ethical issue is addressed in a wider arena and offers the public a possibility to be involved actively. Public debate is often conducted formally as no adequate procedure exists to ensure that the public is informed. In complex issues, such as genetic research, the public should have access to proper information in order to participate effectively in the debate.
Article 26 - Transnational Practices
102. Article 26 deals with transnational research, which is increasing due to international co-operation between the members of extensive research consortiums. Considering the cultural and legal diversity of the societies involved, different segments of research may be conducted in different countries. It is, however, essential that each of these countries be involved in the ethical assessment.

PROMOTION AND IMPLEMENTATION OF THE DECLARATION

Article 27 - Bioethics Education, Training and Information
103. Article 27 underlines the importance of bioethics education, ethics training and information. Trained staff is essential for the proper functioning of national ethics committees. Bioethics education, training and information are obligations that are imposed on States. The overall objective of the Article is to reinforce and increase the capacities of Member States in the area of ethics education.

Article 28 - Solidarity and International Cooperation
104. Today the international dimensions of health care are more significant than ever. In the field of international research co-operation, in the case of rare diseases which are neglected by health care systems at the national level, in the domain of the AIDS-prevention, ethical dimensions of health care frequently go beyond national frontiers.
105. Solidarity between and among individuals, families, groups and communities, with special regard for those rendered vulnerable, should be of special concern in decisions and practices within the scope of this declaration.

Article 29 - Role of States
106. The present declaration provides principles that can also serve as contours for legislation, regulation, and policy decisions within the Member States. The interpretation and implementation of these principles require the active participation of States.

Article 30 - Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)
107. The International Bioethics Committee (IBC) and the Inter-governmental Bioethics Committee (IGBC) shall contribute to the dissemination of the principles set out in the declaration and shall regularly organize consultations in the domain of the declaration. The IBC provides the only global forum for in-depth bioethical reflection by exposing the issues at stake. It does not pass judgement on one position or another. Instead, it is up to each country, and particularly to lawmakers, to reflect societal choices within the framework of national legislation and to decide between the different positions.
108. To guarantee that the declaration remains a living instrument it is necessary that States provide Reports every five years to the Director-General of UNESCO. The aim of the Reports should be to disseminate information on implementation in terms of legislation, regulation, and jurisprudence, as well as in the decisions of national ethics or bioethics committees and other ethics commissions.
Article 31- Follow-Up Action by the UNESCO

109. Standard-setting is always problematic in the field of scientific developments, especially in times of rapid change, as new discoveries cannot be anticipated. If principles are drafted in broad terms with a view to covering changes that have not yet taken place, it may later provide limited direction on what is permitted or proscribed.

110. Concrete normative provisions may soon become outdated, and it can be difficult and time-consuming to change if the initial form is found not to be appropriate. Nowhere is the problem of changing circumstances more apparent than in the field of biomedical sciences. Therefore Article 31 establishes a system of periodic follow-up: five years after its adoption the declaration shall be examined in the light of scientific and technological development and, if necessary, shall be revised in accordance with UNESCO's statutory procedures.

111. The provision of Article 31c is especially important in view of the previous observation that in bioethics there are many topics (‘specific issues’) that are highly controversial at the present moment. The formulation of General Principles in this declaration therefore is the starting-point for a process of consensus-formation which aims at reaching agreement on certain topics over time, so that they can be included in future revisions of the declaration, thus gradually expanding its scope.

Article 32- Denial of Acts Contrary to Human Rights, Fundamental Freedoms and Human Dignity

112. The scope of application of the principles mentioned in this declaration may overlap with some of the principles in human rights. However in the assessment and interpretation of the principles neither the procedure nor the outcome of the decision shall be contradictory to human rights, fundamental freedoms and human dignity.