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**EXPLANATORY MEMORANDUM ON THE ELABORATION  
OF THE PRELIMINARY DRAFT DECLARATION  
ON UNIVERSAL NORMS ON BIOETHICS**

This document provides background information on the elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics (SHS/EST/CIB-EXTR/05/CONF.202/2) and presents the provisions contained therein. The Explanatory Memorandum is not an authoritative interpretation of the draft declaration. It aims at facilitating the debate and provides information to clarify the object and purpose of the declaration and to better understand the scope of its provisions.

Division of Ethics of Science and Technology

(SHS-2005/CONF.204/CLD.2)

## **I. INTRODUCTION**

1. At the beginning of the twenty-first century, the increasingly complex areas of medicine and various life sciences are 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 within a context of cultural pluralism inherent in bioethics. This involves the identification and promotion of universally shared values and the stimulation 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. In 2002 UNESCO further reinforced the importance of this area of work by making ethics one of the five priorities of the Organization.
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 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 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 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 during the process 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. 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 those most critical of technological advances, must develop a response - be it supportive or controlling - to the emergence of new technologies, including biotechnology. To do nothing is to make a decision.

11. The Drafting Group also stressed the importance of taking international human rights legislation as the essential 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 of UNESCO. This could be emphasized by including the phrase ‘human rights’ in the amended title. A similar approach can be observed in the title of the Resolution 2003/69 on Human Rights and Bioethics of the United Nations Commission on Human Rights of 25 April 2003.

12. A most important achievement of the draft declaration is that it anchors the principles that it espouses firmly in the rules governing human dignity, human rights and fundamental freedoms. Bioethics has hitherto developed substantially along two broad streams. One of these, present since the ancient times, derives from reflections on medical practice and on the conduct of medical professionals. The other, conceptualized in more recent times, has drawn upon the developing international human rights law. One of the important achievements of the declaration is that it seeks to unite these two streams. It clearly aims to establish the conformity of bioethics with international human rights law.

### **III. PREAMBLE**

13. The declaration 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 human genome sequences.

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

15. 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 these three instruments are especially relevant since they identify acknowledged principles and standards commonly adopted at the international level.

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## **GENERAL PROVISIONS**

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### **Article 1 – Use of Terms**

16. 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 Van Rensselaer Potter in 1970 who advocated a comprehensive and global view of bioethics; on the

other hand, André E. Hellegers 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 human 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 much of the theory and practice of bioethics.

17. In the Fourth Outline of the 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".

18. During the Joint Session of the International Bioethics Committee and Intergovernmental Bioethics Committee (IGBC) held on 26–27 January 2005 participants considered the definition in the Fourth Outline too academic. During the debate a new definition has been developed with a stronger focus on policy. Instead of the term 'field of study' the expression 'study and resolution' of ethical issues was adopted. This textual change acknowledges that bioethics can serve as a tool for finding solutions for ethical dilemmas in the field of life sciences and social sciences. According to the new definition, bioethics refers to the systematic, pluralistic and interdisciplinary study and resolution of the ethical issues raised by medicine and the life and social sciences as applied to human beings and their relationship with the biosphere, including issues relating to the availability and accessibility of scientific and technological developments and their applications.

19. *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 'molecular life sciences'). Broadly speaking, life sciences include any study or research discipline that contributes to the understanding of life processes. Ethical arguments can apply to entities that are unable to argue or to act on the basis of arguments, including other species or the biosphere.

20. In the resolution of bioethical issues bioethics increasingly relies on different fields of *social sciences*, such as anthropology, psychology, political science, sociology. A corpus of evidence is emerging showing the importance of looking, in our analysis to the non-biological determinants of health. Many issues have to take into consideration cultural and spiritual diversity. For example, the genetic studies of populations have increased the importance of involving social sciences.

21. Bioethics applies to *human beings* and their relationship with the biosphere. While the notion of 'person' is defined in domestic law, human beings frequently appear in international documents and more recently in legal instruments related to bioethics. The two notions are often regarded as synonymous. For instance, the American Convention on Human Rights of 1969, states in its Article 1(2) that "for the purposes of this Convention, 'person' means every human being". For the States that signed this Convention, 'human being' and 'human person' are synonymous. However, in the European Convention on Human Rights and Biomedicine the expression 'human being' is used to state the necessity to protect the dignity and identity of all human beings.

22. The second term defined in Article 1 is '*bioethical issue*'. Although it adds only the word 'issues' to bioethics, it facilitates reference to the questions relevant within the scope of the declaration.

23. The third term in Article 1 is '*decision or practice*', that is a decision or practice arising within the scope of this declaration involving bioethical issues. The principles of the declaration refer to this notion when the phrase 'any decision or practice' is used, as it is in the Articles 4 to 15, and when conditions for implementation are specified in Articles 16 to 23.

## Article 2 – Scope

24. The scope of the Declaration is set out in Article 2. The principles of the Declaration apply as appropriate and relevant at two different levels: (i) individuals, families, groups and communities who are affected by these decisions, and (ii) those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or states. The list is not exhaustive.

25. Ethics is a quintessentially human activity. Human beings not only develop ethical arguments but they are also the only entities that can act on the basis of such arguments. Decisions in the field of bioethics, often require the contribution of multidisciplinary expertise. However, lay people should also be involved in the decision-making process. Bioethics is not solely a matter for experts.

26. 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 principles in the declaration are human beings.

27. During the elaboration of the declaration, especially during the consultation with Member States, a list of topics was adopted to provide for the possible content and scope of the declaration. In contemporary bioethics there are many specific issues that require regulation, with a view on future advances. 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, notably the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data.

28. Consequently, the Drafting Group arrived at the conclusion that *principles and conditions for implementation* should be formulated, which would then provide a basis for developing specific legislation within the Member States and would also stimulate reflections, decision-making, and teaching on ethics at local and regional levels. This was considered to be the first and urgent task. Formulation of principles will 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 or of future instruments that are considered after the declaration has been adopted.

## Article 3 – Aims

29. The declaration is not intended to conclude ongoing bioethics debates. Instead, its major aim is to inspire and stimulate further ethics debates and their resolution within the Member States in order to expand the scope of this declaration and its usefulness. In the early stages of the development of bioethics it would have been impossible to reach consensus on almost any issue or even many of them, whereas given time consensus may emerge in several areas and regarding several principles. Further consensus-formation can be expected in the future.

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. Therefore the declaration identifies seven major aims and each is closely related to the others. First, it provides a universal framework of fundamental principles and conditions for implementation designed to guide Member States in the formulation of their legislation and policies in the field of bioethics. Second, the declaration promotes respect for human dignity and the protection of human rights and fundamental freedoms. Third, it recognizes the benefits derived from scientific and technological developments. Fourth, the declaration fosters dialogue. Fifth, it

also aims to promote equal access to scientific developments by facilitating the greatest possible flow and sharing of knowledge on scientific and technological developments and by emphasizing the value of benefit-sharing. Sixth, the declaration aims to recognize the importance of respect for biodiversity. And seventh, it aims to safeguard and promote the interests of present and future generations in this context.

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## PRINCIPLES

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32. Articles 4 to 15 lay out ethical principles that address policy makers, health care providers and different professional groups and bodies as defined in Article 2. Each of the principles provides guidelines for decisions and practices within the scope of the declaration and therefore, in these articles the word ‘shall’ is applied. In cases when the declaration contemplates that Member States will implement its principles, the word ‘should’ is used; when UNESCO itself is committed to the implementation and promotion of the declaration, the word ‘shall’ is used, indicating a more binding engagement.

33. Principles always require further interpretation since the norms implicit in principles have to be translated into concrete laws, policies, guidelines and practices.

34. Ancient ethical codes were often expressed in the form of an oath to be taken by relevant actors. 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 and the human rights treaties that have followed it. 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 consequentialist theories.

35. Despite the general nature of their expression, principles can serve as sources of legislation, policy, and individual decision-making. Moreover, in comparison with concrete rules, principles may better accommodate rapid advances and changes in the biomedical sciences and in consequential technologies.

36. In previous drafts of the declaration, a distinction was made between ‘fundamental’ and ‘derived’ principles. In the phase of revising the previous drafts and taking into account comments provided to the Drafting Group, the foregoing distinction was eliminated in order to avoid any suggestion of a hierarchy among the principles.

37. The declaration makes a distinction between (1) the principles directly related to human dignity such as respect for human rights and fundamental freedoms, benefit and harm, autonomy, consent and confidentiality; (2) the principles concerning the relationships between human beings, such as solidarity, cooperation, social responsibility, equity, justice, cultural diversity; and (3) the principles governing the relationship between human beings and other forms of life and the biosphere, such as responsibility towards the biosphere. The order of the principles in the declaration therefore follows a particular rationale and endures a systemic approach.

38. These principles represent different rational justifications for human actions. None of them provides an overriding justification. This is a major characteristic of ethics. If there were one fundamental principle, ethics would be a simple undertaking because all human actions could be justified in terms of one principle only. What makes ethics complicated is that several principles may apply to a given decision, The decision-maker has to balance and weigh arguments continuously in order to determine the principled course of action derived from the reconciliation of them all. This is also the justification for the formulation of Article 29 which explains the process involved.

39. The rationale followed in the draft declaration is to present principles in the following way: they determine gradually widening obligations and responsibilities in relation to the individual human being itself; to another human being; to human communities; to humankind as a whole; and towards all living beings and their environment.

#### **Article 4 – Human Dignity and Human Rights**

40. 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. Showing disrespect to human dignity could lead to the instrumentalization of the human person.

41. Another feature of human dignity is emphasized in Article 4(b) which states that the 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 latter 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 must be reconciled in given cases with other principles, such as the principle of solidarity and justice.

42. 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.

43. There are many different views on the relation between human rights and bioethics. Though law and ethics are different disciplines, declarations and documents on bioethics should be in harmony with human rights.

#### **Article 5 – Equality, Justice and Equity**

44. Article 5 deals with three notions closely connected with one another. ‘Equality’ in a legal sense refers to the equal treatment of individuals in a similar situation while the term ‘equity’ refers to a discretion, which serves as a corrective mechanism to formal equality by looking at the special circumstances of particular cases. ‘Justice’ in the philosophical sense is a normative principle that refers to a judgement on the arrangement of institutions, society, groups of individuals. A common definition of justice could be “treating the equal equally and the unequal unequally”.

45. In Article 1 of the Universal Declaration on Human Rights, the concept of equality was articulated in the following way: “All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood”. In the present declaration, this concept of brotherhood, expressed in a contemporary way, is further elaborated in Article 12 on *Solidarity and Cooperation*.

46. Principles of justice are essential to the structure of a constitutional democracy. Fairness and due process are part of democratic legal systems mandated by international human rights law 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 practices in the field of bioethical issues, such as in allocating health care services and setting priorities in health care, both in general and in individual cases.

#### **Article 6 – Benefit and Harm**

47. The title of this Article in the Fourth Outline was “Beneficence and Non-Maleficence”. During the IBC–IGBC Joint Session held in January 2005, a general position developed favouring the avoidance of the use of these terms for two reasons. One was that these terms are not used by either

policy-makers or the general public in various cultures and languages. Second, the two principles that originated from the ancient maxim of ‘do good’ and ‘do no harm’ (*primum non nocere*) mean something different when they are combined together. Therefore, the principle was changed by stating that any decision or practice shall seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice. This formulation is very similar to Article 6 on Risk and Benefits in the Additional Protocol to the Convention on Human Rights and Biomedicine Concerning Biomedical Research adopted by Council of Europe that states that “research shall not involve risks and burdens to the human being disproportionate to its potential benefits”.

### **Article 7 – Respect for Cultural Diversity and Pluralism**

48. Cultural diversity refers to the manifold ways in which the cultures of different 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.

49. Respect for cultural diversity requires careful implementation. If ethical standards are dictated and simply copied in various legal systems, without adequate interpretation and adaptation, they may remain as mere legal transplants that will not function properly with other elements of bioethical principles 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.

50. According to the Universal Declaration on Cultural Diversity of UNESCO, 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.

51. During the written consultation process, some countries expressed their fear that respect for cultural diversity could easily be used to override any other moral consideration. The text of the declaration therefore adds the proviso (as in the Universal Declaration of Cultural Diversity) that this principle cannot be used to limit the application of the other universal principles: “such considerations shall not 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”.

52. From Articles 30 and 31 of the declaration it also follows that cultural diversity cannot call into question universal human rights.

### **Article 8 – Non-Discrimination and Non-Stigmatization**

53. Article 8 of the declaration does not deal with all forms of legitimate distinctions between people. It focuses only on unlawful, unfair or unjustifiable discrimination between people based on any grounds such as gender, age, ethnicity, disability or other physical, mental or social conditions, diseases or genetic characteristics and the like. The list is not closed.

54. 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.

55. Discrimination, both in its direct and indirect forms, treats a morally neutral and immutable characteristic (such as skin colour, gender, genetic or similar 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.



56. The history of medical research shows - even in the recent past - a disturbing pattern of discrimination against different groups, including 'races', ethnic minorities, and women. During the conceptualization of research and the establishment of control groups, culturally, morally or legally problematic categories may be used, and the avoidance of discriminatory practices requires communication between the relevant disciplines.

57. The elimination of discrimination is to be attained in the different areas of health care, biomedical research and health policy formulation. Not only direct forms of discrimination, (when one group of individuals is positioned in disadvantageous situation) but also the various indirect forms should be eliminated.

58. Discrimination may distort scientific progress. For instance, the routine exclusion of women from research trials has led to the fact that many of the conditions specific to women remained unknown or uninvestigated and that discoveries that were applicable to men were simply assumed to be applicable for women patients. There are many similar instances affecting stigmatised or disadvantaged groups.

59. 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 significant role.

#### **Article 9 – Autonomy and Individual Responsibility**

60. Respect for personal *autonomy* is strongly linked to and, according to certain interpretations, derives from the notion of human dignity. It is directly derived from binding international human rights law. Individuals cannot be instrumentalized and treated merely as means to a scientific end; they should be granted the authority to make autonomous decisions in all aspects of their lives where their decisions do no harm to others.

61. Respect for autonomy involves not just a respectful attitude but also respectful action. However, autonomy, in this interpretation, is not simply an *invested* right. It also has the dimension of *responsibility* towards others. Article 9 reflects the right of each person to make individual decisions, whilst at the same time respecting the autonomy of others. Some experts wanted to reinforce the emphasis on responsibility by including in Article 9 reference to the duty to take such responsibility. However that formulation seemed to be too forceful and might indicate a possible erroneous interpretation of autonomy which is not a synonym of 'freedom' or 'liberty'. Autonomy refers to the concept of acting in accordance with voluntarily accepted principles but it does not liberate the individual from taking responsibility for his or her actions.

#### **Article 10 – Informed Consent**

62. Articles 9 and 10 are interconnected in the sense that autonomy and responsibility are the basis of informed decisions in the field of bioethics. Article 10 affirms the relevance of information in different cases of informed consent.

63. *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 affecting themselves. Though the doctrine of informed consent is largely a creation of court decisions, it rests ultimately on ethical foundations.

64. As an outcome of the debate of the IBC–IGBC Joint Session in January 2005, Article 10 is more focused and formulates a general rule only. The article deals with the concept of informed consent in two major fields. 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.

65. 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. The term ‘free’ means voluntary consent “without inducement”.

66. According to paragraph b) regarding a decision or practice related to medical diagnosis and treatment the person concerned must receive appropriate information about the decision; must 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 reflected in other international and various national legal instruments - an affected individual has to receive relevant, structured and individually tailored information that makes it possible for that individual to make a decision on whether or not to accept medical treatment, as well as to understand and cope with the diagnosis.

67. Paragraph b) goes beyond the requirement of consent by emphasizing the ongoing participation of persons in such decisions as affect them. Ongoing participation, on one hand, refers to an active role of participants (patients); on the other hand, it also indicates that informed consent is no longer a one-step requirement before the treatment, as communication should be continuous throughout the treatment.

68. Based on the domestic law, consent may take different forms, such as *explicit*, *substituted* (e.g. in case of terminally ill patients), and *presumed consent* (e.g. emergency situations).

69. Paragraph c) states that special protection shall be given to persons who do not have the capacity to consent. Such protection shall be based on ethical and legal standards, consistent with the principles set out in this Declaration and adopted by States. The domestic law of Member States should provide for consent to be given by members of the family, an official or court where the person concerned incapable of doing so.

70. Some recent advances in science, such as genetic testing for late onset diseases, have raised increasing concerns about the right *not* to be informed. As the Declaration deals with bioethics in general, this issue was regarded as too detailed to be included among the principles. Article 5(c) of the Universal Declaration on the Human Genome and Human Rights already recognised this right by stating that “[t]he right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected”. A special Article, Article 10 is dedicated to this question in the International Declaration on Human Genetic Data, titled “The right to decide whether or not to be informed about research results”.

## **Article 11 – Privacy and Confidentiality**

71. A 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.

72. *Confidentiality* refers to a special and often fiduciary relationship, such as that 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.

73. The importance of privacy has been recognized in numerous legal instruments, such as the OECD Guideline on the Protection of Privacy and Transborder Flows of Personal Data adopted in 1980; the Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data; and the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data.

## **Article 12 – Solidarity and Cooperation**

74. Article 12 reflects the commitment that the declaration is based not only on the individualist concept of *rights* but also recognizes the importance of *solidarity* between individuals and across communities.

75. Serious inequalities in access to health care worldwide increase the importance of including solidarity as one of the principles of the declaration. 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 minorities, indigenous people, by providing access to reproductive health services available according to law and to children in guaranteeing their access to health care.

## **Article 13 – Social Responsibility**

76. The Preamble to 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. The expression of the social responsibility principle is designed to address the attention of policy makers in the field of medicine and life sciences to the practical concerns of bioethics, as viewed in most States and by general public.

77. Article 13 is included in the declaration in order to reflect a new agenda for bioethics, taking into account a wider social dimension of scientific progress. The recognition of reproductive health and the health of children is one element of this dimension. The relevance of reproductive health can be seen by looking at health statistics: every year some eight million women suffer pregnancy-related complications and over half a million die. In developing countries, one woman in 16 may die of pregnancy-related complications compared to one in 2,800 in developed countries. Being aware of the statistical figures of maternal mortality levels is not enough; social responsibility is needed to contribute to the prevention of unnecessary deaths of large numbers of women and children.

78. Five specific elements were singled out: access to quality health care, including reproductive health care and the health of children; access to adequate nutrition and water; improvement of living conditions and the environment; and the elimination of the marginalization and exclusion of persons on the basis of any ground, and reduction of poverty and illiteracy. These were judged as priority and universal areas of decision to be taken into assessment, whenever relevant and appropriate in bioethical decision-making. The list is not closed.

79. Elimination of the marginalization and exclusion of persons on the basis of any ground, including gender, age, ethnicity and disability was recognized as different from elimination of discrimination as stated in Article 8. 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 the benefits of scientific development.

## **Article 14 – Sharing of Benefits**

80. *Sharing of benefits* often appears in various legal documents on genetic resources. In its Article 1, the United Nations 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. Article 14 of the present Declaration closely follows the structure of that Article.

81. The present declaration goes beyond the scope of genetics by including the sharing of benefits resulting from scientific research and its application in general. Of course, such sharing will in practice take place within the framework of international law and domestic law governing such matters. See Article 30.

82. Six concrete elements and one general element are enlisted as forms of sharing benefit: (1) special and sustainable assistance to the persons and groups that have taken part in the research; (2) access to quality health care; (3) provision of new diagnostics facilities for new treatment or medical products stemming from the research; (4) support for health services; (5) access to scientific and technological knowledge; (6) capacity-building facilities for research purposes; and (7) any other form consistent with the principles set out in the declaration.

83. Paragraph b) sets out the ways in which these forms of benefit sharing may be implemented.

### **Article 15 – Responsibility towards the Biosphere**

84. The Preamble to 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 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, this article affirms that human beings have responsibilities towards other forms of life in the biosphere.

85. The concept of *human relations with the biosphere* 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 in common bioethical reflections. 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 life style and in social and economic policy decisions.

86. 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.

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## **CONDITIONS FOR IMPLEMENTATION**

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87. Conditions for implementation describe the procedural aspects 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 appear to be relevant at the same time. In earlier drafts the term ‘procedural principles’ was applied but the Drafting Group felt that the word ‘procedural’ might, at least in some languages and cultures, have strong judicial connotations and therefore adopted the term ‘implementation’ to avoid any such restrictive connotation.

88. Conditions for Implementations address Member States and therefore Articles 16 to 23 employ the word ‘should’ instead of ‘shall’. The principles are expressed in the obligatory ‘shall’ because of the universal and fundamental nature of their norms. When it comes to implementation - whether by individual decision makers, institutions or Member States - the declaration recognizes the need to accept greater flexibility than in the expression of the principles.

89. In contrast with the principles in Articles 4 to 15 that provide guidance for the content of decision-making, conditions for implementation are not thematic and do not deal with the content of ethics decisions, but rather refer to the process leading to ethically acceptable decisions in various fields of bioethics.

90. The declaration identifies eight conditions for implementation: (1) decision-making; (2) honesty and integrity; (3) transparency; (4) periodic review; (5) ethics committees; (6) promoting public debate; (7) risk assessment, management and prevention; (8) transnational practices.

### **Article 16 – Decision-Making**

91. 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.

92. When a decision has to be made about an issue that is within the scope of the declaration, a fair, unbiased procedure shall be initiated - where different positions are canvassed and taken into account within a reasonable time. Article 16 of the declaration prescribes that any decision or practice within the scope of the declaration should 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.

93. History provides numerous examples of the fact that *unethical* scientific research is usually 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.

94. The declaration identifies six main criteria for achieving the goals of this principle: (1) the decision and practice should be carried out following full and free discussion and (2) in accordance with fair procedures; (3) they should be made or carried out on the best available scientific evidence; (4) due regard should be paid to different information available; (5) appropriate procedures of risk assessment should be considered rigorously and in a principled manner; and (6) individually tailored decision-making should be made.

95. In the field of bioethics, standard-setting and political decision-making require interdisciplinary consultations and the widest possible *involvement of the public*. The participation of lay-people and non-experts in each decision-making is also reflected in the provisions of Article 2.

### **Article 17 – Honesty and Integrity**

96. Article 17 prescribes three elements of decision-making and practice within the scope of the declaration: (1) professionalism, honesty, integrity; (2) declaration of all conflicts of interests; (3) and due regard to the need to share knowledge.

97. *Conflict of interest* refers to a clash between the public interest or professional and legal duty and the private (often but not necessarily pecuniary) interest of the individual concerned. It commonly arises in a context where public officials and fiduciaries have a special relationship to, or interest in, a specific matter. Conflict may occur between public, academic and business interests, or between medical, scientific and economic interests.

### **Article 18 – Transparency**

98. Transparency is a very important condition for principled decision-making and sound practice within bioethics. 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, 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 the procedures and methodologies of science and technology more transparent and accessible to the public.

99. Article 18 necessarily refers to Article 11 as some decisions in the field of bioethics have a confidential nature. For example, in decisions on the medical treatment of an individual, personal information provided by the patient should necessarily be taken into account. Sometimes legally protected commercial confidentiality may impose restrictions on publicity to outsiders. The information provided should be regarded as private and confidential matter. The structure of the declaration makes this distinction evident by enlisting *privacy* and *confidentiality* among principles, while including *transparency* at the level of implementation of the principles. By adopting appropriate expedients implementation that involves considerations of privacy and confidentiality can usually avoid the risks of disclosure whilst achieving a desirable level of transparency and public participation and knowledge.

### **Article 19 – Periodic Review**

100. Article 19 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 wider society. Periodic review is a profound, systematic dialogue with society. Its aim goes beyond providing up-to-date information, as it also promotes continuous ethical social reflections on scientific knowledge.

101. The declaration distinguishes four target groups with whom regular dialogue should be maintained: (1) persons affected by these decisions or practices; (2) members of relevant disciplines; (3) appropriate bodies; and (4) civil society.

### **Article 20 – Ethics Committees**

102. Article 20 embraces both ethics and bioethics committees, on different levels and in different fields of research ethics; policy-making, quality assurance, and peer-review committees; utilization review and risk management committees; and scientific-review committees.

103. This reflects a current trend in which bioethics committees, however officially named, 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 such ethics committees in the fields within the scope of the declaration, including the domain of research ethics, and, furthermore, to strengthen the role of such committees in their interpretation of the principles of bioethics. In this respect, such committees have an essential role to play in the implementation of the declaration.

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

### **Article 21 – Promoting Public Debate**

105. This obligation is imposed on Member States and not just on ethics and bioethics committees. As Articles 16 to 23 follow the procedures for making a decision on ethical issues, in public debate, ethical issues are addressed in a wider arena and offers the public a possibility to be involved actively. Public debate is often a formality as most of the time no prescribed procedure exists to ensure that the public is informed. In complex issues, such as genetic research, the public should have access to proper and necessary information in order to participate effectively in such debate.

## **Article 22 – Risk Assessment, Management and Prevention**

106. Article 22 deals with two different scenarios. Paragraph a) deals with those cases in which there is evidence of serious or irreversible damage to public health or human welfare. Paragraph b) concerns situations in which there are threats of serious or irreversible damage to public health or human welfare. Paragraph b) describes the procedures to be followed in cases where there are new scientific and technological developments that *may* lead to serious or irreversible damage to public health and human welfare or to the environment, although the probability of such harm occurring is not known with scientific certainty.

107. 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 may vary from accepting the development, regulating and monitoring the development, accepting a moratorium, or prohibiting the development.

108. The measures taken under Article 22 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 23 – Transnational Practices**

109. Article 23 deals with transnational research, which is increasing because of international cooperation between the members of extensive research consortiums operating in different States. Free movement of scientists and experts for exchange ideas is essential to promote science.

110. The incidence of cases of biopiracy and international trafficking of organs have already led to calls for international measures. Nevertheless, 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 of the research that is undertaken and in the measures that follow from it. This involves the need to establish a practice of submitting research projects to an ethics committee in every research location within each Member State.

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## **IMPLEMENTATION AND PROMOTION OF THE DECLARATION**

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### **Article 24 – Role of States**

111. When the Declaration addresses States it applies the word ‘should’ instead of ‘shall’, since the declaration cannot impose obligations on States in their activities to implement the declaration. The present declaration provides principles that may 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. Accordingly, the Declaration invites Member States to take appropriate measures, to encourage the establishment of ethics or bioethics committees, and to create processes for risk assessment.

### **Article 25 – Bioethics Education, Training and Information**

112. Article 25 underlines the importance of bioethics education, ethics training and information. Trained staff is essential for the proper functioning of national ethics committees, however officially named. Education, training and information in the fields relevant to bioethics should be organized by the Member States. The overall objective of the Article is to reinforce and increase the capacities of Member States in the relevant area of ethics education.

### **Article 26 – International Cooperation**

113. The international dimensions of health care today are more significant than ever before. Rare diseases that are sometimes neglected by health-care systems at the national level may be very dangerous in other parts of the world, which requires international cooperation of scientific research. In the case of HIV/AIDS-prevention, for example, ethical dimensions of health care frequently go beyond national frontiers.

114. Cooperation between and among individuals, families, groups and communities, with special regard for those rendered vulnerable, should be of special concern in the making of relevant decisions and the establishment of appropriate practices within the scope of this declaration.

### **Article 27 – Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)**

115. The Declaration applies a stronger word when it creates obligations addressed to UNESCO. In this article the word 'shall' is used. The International Bioethics Committee and the Intergovernmental Bioethics Committee shall contribute to the dissemination of the principles set out in the declaration and shall regularly organize consultations relevant to the declaration. The IBC provides the only global expert forum for in-depth general, multidisciplinary bioethical reflection by exposing the issues at stake. It does not make binding rulings on specific bioethical issues. Instead, it is left to each country, and particularly to lawmakers, to reflect societal choices within the framework of national legislation and to decide between the different positions, guided by the principles expressed in the declaration.

116. To guarantee that the declaration becomes an effective, and remains a living, instrument it is considered necessary that Member States provide reports every five years to the Director-General of UNESCO. The aim of the reports should be to disseminate information on the implementation of the principles contained in the declaration: in terms of legislation, regulation, and jurisprudence, as well as in the decisions of national ethics or bioethics committees and other ethics or similar commissions.

### **Article 28 – Follow-Up Action by the UNESCO**

117. 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, they may later provide limited direction on what is to be permitted or proscribed. If they are drafted with high specificity and particularity, they may be quickly overtaken by advances in science and technology.

118. Concrete normative provisions may soon become outdated, and it can be difficult and, especially in case of international instruments, time-consuming to secure 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 28 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.

119. The provision of Article 28(c) is especially important in view of the previous observation that in bioethics there are many 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 promoting agreement on certain topics over time, so that they can be included in future revisions of the declaration, thus gradually expanding its scope.



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## OPERATION OF THE PRINCIPLES AND DECLARATION

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120. *Operation of the Principles and the Declaration* provides guidelines for the interpretation of the principles in the declaration and offers guidance for the cases when the principles set in the declaration are in conflict with one another. Articles 29 and 30 are applicable to the interpretation of and restrictions on the principles; Article 31 applies to the entire declaration.

### **Article 29 – Interrelation and Complementarity of the Principles**

121. In the domain of bioethical questions, consensus on specific issues will require the balancing and weighing of principles. It is the nature of bioethics that several principles may apply at the same time when a decision-maker is 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 analyzing the arguments in order to determine how the principles will operate by interaction with one another.

122. 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 and applicable principles need to be taken into account in order to reach a reasoned conclusion about the ethical solution.

### **Article 30 – Restrictions on the Principles**

123. Restrictions may be placed on the operation of the principles set out in the declaration only in accordance with international human rights law, and then only if they are prescribed by domestic law and only when such restrictions are 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 possible restrictive measures, *proportionality* has to be respected, because, when a restriction is considered to be necessary in accordance with the foregoing principles, rights derived from principles may then be restricted only in the least restrictive manner and only to an extent proportional to the legitimate end of the restriction.

124. Since Article 30 formulates exceptions in restricted circumstances and for restricted purposes, no exceptions are mentioned in the formulation of the principles themselves. Confronted with a specific bioethical problem, an ethically justified solution is usually only attained by balancing the relevant and applicable principles. The solution may be 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 by domestic law. Even so, some limitations always apply since the restrictions must be consistent with international human rights law and should be prescribed by domestic law. This formulation is common to international instruments and seeks to recognize the reality of domestic law whilst reflecting the obligations of international human rights law.

### **Article 31 – Denial of Acts Contrary to Human Rights, Fundamental Freedoms and Human Dignity**

125. This article provides an interpretive rule to be observed in giving meaning to the entire declaration. The scope of application of the principles mentioned in this declaration may overlap with some of the human rights principles. 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. In this way the declaration closes with a strong affirmation that its terms are to be placed squarely within the context of international law and human rights. It is this harmonization of bioethical principles and human rights norms that constitutes a major achievement of the declaration.