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## **Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics**

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## **I. Introduction**

1. By virtue of 31 C/Resolution 22 entitled “Bioethics Programme: Priorities and Perspectives”, the General Conference of UNESCO, at its 31st session, invited the Director-General to submit to it at its 32nd session in 2003 “*the technical and legal studies undertaken regarding the possibility of elaborating universal norms on bioethics*”.
2. Furthermore, the participants in the Round Table of Ministers of Science on “Bioethics: International Implications” (Paris, 22-23 October 2001) invited UNESCO “*to examine the possibility of developing, starting from the Universal Declaration on the Human Genome and Human Rights, a universal instrument on bioethics, in association with national ethics committees and similar bodies, in cooperation with the governments of Member States and relevant international organizations, chiefly the United Nations, the specialized agencies of the United Nations system and other competent organizations at the international and regional level, and in consultation with the public and private sectors, the scientific community and representatives of civil society*” (par. 7 (viii) of the Communiqué of the Round Table).
3. At its Eighth Session (Paris, 12-14 September 2001), the International Bioethics Committee (IBC) therefore decided to include this issue in its work plans and to set up an ad hoc Working Group (see Composition of the Working Group in Annex). During its two meetings, in April 2002 and March 2003, the Group discussed the possibility of drafting a universal instrument on bioethics. A preliminary report was reviewed by the IBC at its Ninth and Tenth Sessions (Montreal, 26-28 November 2002 and Paris, 12-14 May 2003).
4. This report, which is based on the discussions in the Working Group and the IBC, examines the feasibility of an international instrument on bioethics within the context of existing international legal instruments relating to the subject (II-III). It then proceeds, without being exhaustive or prescriptive, to examine some issues in bioethics that could be addressed in an international instrument to illustrate how the elaboration of such an instrument could contribute and support international efforts being made to provide ethical guidelines in matters related to recent scientific developments (IV). Before presenting the conclusions and recommendations of the IBC, the Report explores the likely form and scope of an instrument (V) as well as its value in terms of education, information dissemination, awareness-raising and public debate (VI).

## **II. Present Context: Existing International Legal Framework**

5. Certain key texts, such as the Hippocratic Oath and other medical traditions, have defined some of the principles and forged the corresponding concepts on which bioethics is predicated. However, modern bioethics is indisputably founded on the pedestal of the values enshrined in the Universal Declaration of Human Rights (1948). Other texts of different legal force have established rules for the protection of persons in the wide field of biomedicine. These include the principles of Nuremberg adopted by the United Nations General Assembly in 1947, the Declaration of Helsinki (1964) of the World Medical Association (WMA) – some of whose features are spelled out in greater detail in the Declarations of Tokyo (1975), Venice (1983) and Hong Kong (1989) – and the International Ethical Guidelines for Biomedical Research Involving Human Subjects (1992) prepared and recently revised by the Council for International Organizations of Medical Sciences (CIOMS). Finally, given the magnitude of the ethical issues raised by genetics and thanks to the political will expressed by the

international community, UNESCO has contributed to the formulation of fundamental principles in bioethics through the Universal Declaration on the Human Genome and Human Rights, which was adopted unanimously and by acclamation by the General Conference in 1997 and endorsed by the United Nations General Assembly in 1998.

6. At the regional level, the only existing conventional instrument is the Convention for the Protection of Human Rights and the Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, which was drawn up within the framework of the Council of Europe, adopted in 1996 and in force since 1997. An additional Protocol is already in force and another is open for signature. The main purpose of the Convention (Art. 1) is to “*protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedom with regard to the applications of biology and medicine*”. Article 2 states that “*the interests and welfare of the human being shall prevail over the sole interest of society or science*”. On the other hand, the Charter of Fundamental Rights of the fifteen countries of the European Union, adopted at the Nice Summit in 2000, includes other points of bioethical interest that are related not only to biology and medicine: the right to life (nobody can be condemned to capital punishment); the right to physical and mental integrity, to freedom and personal security; the refusal of torture and inhuman punishments or treatments, of slavery and forced labour, but also include “positive rights” connected with fundamental needs, such as health and education, and that demand action and implementation of public policies. The American Convention on Human Rights (1978) and the African Charter on Human and Peoples’ Rights (1981) also contain provisions relevant to bioethics.

### **III. Need for and Feasibility of a Text of a Universal Nature on Bioethics**

7. The need for universal ethical guidelines covering all issues raised in this field is increasingly felt by specialists and decision-makers as well as by civil society and the international community. In this respect, the Declaration on Science and the Use of Scientific Knowledge and the Science Agenda – Framework for Action<sup>1</sup>, adopted in 1999 in Budapest, highlighted the ethical dimension of the present-day development of science and technology.

8. Bioethics, which covers the ethical, legal, social and cultural dimensions of the medical and life sciences, as well as the technologies associated with them, today plays a predominant role in ensuring respect for human dignity and the protection of human rights and fundamental freedoms. The collective response to medical atrocities committed in the name of scientific research in the 1940s gave rise to the Nuremberg Code and highlighted the importance of a transnational approach to ethical reflection. In the early 1970s such reflection developed as a reaction to the medical paternalism often associated with the Hippocratic tradition. During the early phase of bioethical discourse notable developments included in particular a) the transformation of healthcare provider/patient relationship and the emphasis on respect for personal autonomy and informed consent; b) the emergence of the issues of equity and just allocation of healthcare resources, also in relation to the principle of equity; and c) the debates concerning the use of medical technology in organ transplantation, life prolongation, human reproduction and genetics.

9. The focus has since broadened considerably. In addition to issues relating to the beginning and the end of human life, bioethics covers issues raised by the donation of human organs, tissue, cells, and gametes; the scientific, epidemiological, diagnostic and therapeutic uses of genetics; embryonic stem cell (ESC) research; pre-implantation genetic diagnosis

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1. See in particular paragraphs 19 to 22, 40 and 41 of the Declaration and paragraphs 71 to 77 of the Agenda.

(PGD); gene therapy; predictive medicine (including, for example, the problems raised by the fact that early diagnosis does not necessarily go hand in hand with availability of necessary therapies); the introduction of transgenic technology and genetically modified organisms (GMOs) into agriculture and stockbreeding, etc. All these issues concern ethical choices connected with recent progress in biomedical and other sciences that were previously inconceivable or thought to be impossible.

10. Bioethics also deals with the persistent and critical conditions of human beings all over the world and the ethical and legal reflections on birth, child exploitation, gender equality, equality between different human populations, access to cures, disease prevention, death, ecology, the protection of the environment and the responsibilities toward future generations. The debate in bioethics covers two interlacing concerns: (a) the moral values that actually guide the behaviour of individuals and communities and (b) the moral values and priorities that should guide public policies at various levels on these issues. In this context, a truly urgent and universal issue is benefit-sharing and equal access to the advances of science and technology for all humanity.

11. The interrelation among different areas of medicine and the life sciences gives rise to bioethical dilemmas that confuse many people. For example, transgenic technology might open up new horizons in the field of transplant surgery by providing organs that would be compatible with the human body and so integrate the supply of donor organs, but can undermine health security. In addition, certain ethical problems, such as those raised by breakthroughs in techniques of human reproduction or embryology, are set in the various cultural, philosophical and religious bedrocks of human communities. Other problems, such as those raised by advances in genomics and proteomics, have different implications depending on legal traditions or even on the symbolic thinking that has accompanied the evolution of societies for thousands of years.

12. These various problems increasingly concern specialists, civil society and the international community. To the already difficult question posed by life sciences – How far can we go? – other queries must be added concerning the relationship between ethics, science and freedom. A recognized principle is that nobody can limit human knowledge. Indeed, the main ethical principles of science are freedom, rigour, communication and transparency. In light of emerging options being offered by medicine and the life sciences for human health and welfare, bioethics must reflect on (1) the responsible exercise of scientific research and invention to improve the condition of human beings, (2) what is permissible with regard to this exercise and (3) alternative frameworks for arriving at a broad consensus regarding important issues. This reflection must take into account the multidisciplinary character of the discipline and the cultural sensitivities of human communities. It is difficult to conceptually and practically separate scientific knowledge from its methods and its implementation through technologies, but questions arise: which rules should govern experimentation? Who establishes the priorities in technologies, based on what criteria and in whose favour? What is their impact on human welfare, on living organisms, the environment and future generations?

13. States have a special responsibility not only with respect to bioethical reflection but also in the drafting of any legislation that may stem therefrom. It is true that, in matters of bioethics, many States have framed laws and regulations aimed at protecting human dignity and human rights and freedoms. Any denial of human dignity is an unacceptable denial of the rights of the human person and, as such, concerns the entire international community.

#### **IV. Fields that might be Addressed by a Universal Instrument: Illustrating the Need to Find Common Ground in Bioethics**

14. A growing number of scientific practices have extended beyond national borders. The import and export of embryos and embryonic stem cells, organs, tissues and cells have called attention to disparities between policies promulgated in the countries involved. The transborder flow of tissue collections, DNA samples and genetic data has also raised questions about the need for harmony among the pertinent regulations in different countries. The conduct of biomedical research and experiments involving several countries have highlighted the importance of international guidelines that promote the consistency of regulations and policies in developed and developing countries. These practices and experiences point to the need for people of all nationalities and their governments to look beyond their borders in understanding the bioethical issues that are being generated and providing solutions that are fair to all and compatible with the plurality of values and interests of the international community. This section examines some of these issues and explores the ways an international instrument can contribute towards greater understanding.

15. It needs to be emphasized that the examination of issues in the following paragraphs is meant merely to address the question of the feasibility of an international instrument. It does not aim at providing a comprehensive list of issues and neither does it seek to provide specific solutions. The purpose of this limited survey is to illustrate the nature and the range of the problems that confront us and support the search for a common ground that can be the starting point for harmonizing divergent bioethical positions.

##### ***Healthcare***

16. Health has a dual moral value: it is essential for the quality of life and life itself and is instrumental as a precondition for freedom. When disease prevails, the destiny of a person (and even of a nation) is left to external factors and powers and may enter into an irreversible vicious circle of regression. The inequality between the rich and the poor – at the level of individuals, communities and nations – is becoming increasingly deeply felt in the area of health and healthcare, thereby contributing to the desperation and injustice that prevail and continue to increase in other health-related fields such as food, income and education.

17. As healthcare services and medicines become increasingly more expensive, access to them by poor populations becomes more severely compromised. While poor people have at least as much need for these medicines as everybody else, many do not have the resources to guarantee access. In the context of the dreaded diseases currently confronting the world, the obligation to find new and effective ways of dealing with the situation has truly acquired immense ethical significance. Our global society must face the responsibility to use science and technology to promote public health and to equalize access to healthcare and medicines. A universal instrument on bioethics can contribute to the recognition of “*the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*” (Art. 12, International Covenant on Economic, Social and Cultural Rights), as it would make priorities the core and vital needs of persons and the increase of poor people’s access to life-saving drugs and treatments worldwide.

18. As important as the concern about access to healthcare might be, some of the most promising efforts to provide solutions have been controversial. Some countries have claimed that they should be allowed to infringe drug patents in emergencies. For instance, economically struggling governments have resorted to “parallel importation” to allow the purchase of cheap supplies from countries with weak patent laws, thereby undermining the commercial interests of transnational companies that rely on the observance of patents to protect their investments.

Other governments have tried a system of “compulsory licensing”, enabling them to license a local generic manufacturer to make drugs more cheaply or to buy a generic version from another country. A universal instrument on bioethics can begin to address the associated ethical concerns by attempting to provide a framework that would stimulate international institutions (e.g. the World Trade Organization and the World Health Organization) to face the problem and enable different countries to deal with the contradictions that arise.

### ***Human Reproduction and the Beginning of Life***

19. The conjunction of deep changes in the relation between genders and biomedical progress has opened procreative options that challenge predominant values regarding human beings and families. Efforts to exercise control over reproduction have been directed at different ends: to use assisted reproductive techniques in order to have children, or to use medical technologies to prevent pregnancy, or to select against affected offspring. At the same time, researchers have explored ways to enhance life through various methods, including those that involve genetic engineering. These methods have accentuated the fact that human reproduction is a complex phenomenon that has been further complicated by varying cultures, traditions and religious beliefs. New developments have also raised ethical concerns about the rights and welfare of women, children and families. A universal instrument on bioethics can attempt to provide a framework based on the free decisions of parents and the pre-eminent needs and interests of children, for addressing these issues in terms of general principles capable of commanding universal respect.

### ***Genetic Enhancement, Gene Therapy and Genetic Modification***

20. The transfer of genetic material intended to modify pathological and non-pathological human traits has been seen to hold great promise for human beings. While research has mainly sought to find treatments for diseases, parallel efforts have been addressed to the enhancement of traits rather than the correction of deficiencies. Up to this point, experimental results indicate that the process of gene transfer exceeds safe limits for medical intervention. Notwithstanding present limitations, some diseases or conditions cry out for more revolutionary measures than those that are presently available. Considering the crucial role that genes play in relation to the identity of human beings, procedures involving gene transfer easily generate controversy. Ethical questions arise about the meanings of terms such as “normal”, “therapy” and “enhancement”. Tough questions need to be answered about the balancing of risks and benefits, equitable access, the cost of interventions and the consequences of the procedures for human evolution. A universal instrument on bioethics can provide a mechanism for directing people’s attention to essential questions about humanity that human beings ought to address in harmony, mindful of the long term and possibly irreversible implications for the continuing evolution of the human species.

### ***Human Genetic Data and other Personal Healthcare Data***

21. Human genetic data are critically important to the progress of science and medicine and related non-medical and legal purposes. At the same time, the collection, processing, use and storage of such data present potential risks to the people that they pertain to. In particular, human genetic data are imbued with a level of specificity and sensitivity that provide lifelong medical and personal information, both present and future, concerning individuals, families over generations, ethnic groups and descendants. Possible negative consequences include violations of secrecy, private appropriation of data and discrimination at work and in the provision of healthcare.

22. As attention is increasingly drawn toward the sensitivity of genetic data, the problems that may arise from the improper handling of healthcare personal data should not be overlooked. Violations of human rights, fundamental freedoms and human dignity can equally result from the careless and arbitrary use of personal healthcare data. Care needs to be exercised to prevent stigmatisation, discrimination and other forms of injustice arising from the identification of data with specific individuals or groups. A universal instrument on bioethics can highlight the significance of protecting the privacy of people and the confidentiality of their genetic and personal healthcare data while encouraging equitable access to the benefits that these data give rise to, and without impairing the capability of scientists to find ways of maximizing such benefits.

### ***End of Life***

23. Advances in medical science and technology have made it possible for many people to live longer today than at any other period in the history of humanity. However, longer lives are not always healthier. Many people suffer during old age from disease, disability, pain and lack of help. Many people are subjected to overmedication. Many are kept alive through the use of machines even when they have no realistic chances of recovery. This condition raises ethical dilemmas accompanied by a debate on economic consequences. The meaning and significance of life and death are inextricably tied up with culture and tradition and tension exists between the idea that life is sacred and the desire to maintain a certain quality of life. The compatibility of clinical criteria of death with such meaning and significance is a subject of disagreement and controversy, as are the practical issues relating to the possibility of using machines that prolong vegetative life indefinitely. Whatever the nature of the ethical dilemmas that they face, people tend to look for autonomy, help and guidance to ease the burden on their conscience. A universal instrument on bioethics can ease that burden and provide a direction for decision-making that highlights the need to respect human life especially at its most vulnerable moments.

### ***Research involving Human Subjects***

24. The medical and scientific communities' intense endeavour to find the best prophylactic, diagnostic and therapeutic methods to fight disease have continued to result in immense pressure for the participation of human subjects in research. Studies such as those undertaken to combat HIV/AIDS, dreaded diseases and biochemical war materials are highly beneficial and necessary. However, they also put many individuals at great risk. Therefore, there is a need to remain vigilant in the prior review of these activities and the monitoring of their implementation.

25. The increasing globalization of biomedical research has brought to the forefront more ethical issues in the involvement of human subjects. While international collaboration has enabled sponsor countries to conduct research in poor communities with greater convenience, coordination and efficiency, the practice has also highlighted a need for greater vigilance to guard against evolving forms of exploitation. Although international collaborative research represents laudable efforts to address common health concerns, different standards tend to be used in rich and poor countries, and the research design and methodology often put unnecessary burdens on poor people, poor communities and poor countries. Biomedical research has to be conducted in accordance with universal standards.

26. A universal instrument on bioethics can focus on such issues through provisions seeking to promote the recognition of researchers from developing countries as full and equal partners in biomedical studies and to promote an appropriate integration of knowledge and technologies of developed and developing countries. It can also underscore the need to raise the standard of

benefits accruing to participant communities or countries, to promote initiatives for ensuring broad and equitable access and to address approaches for building the capacity of scientists in developing country to become full partners in international research. In view of the numerous guidelines that currently exist concerning the practice, a universal instrument on bioethics can provide unity while recognizing the special challenges posed by the unique histories, cultures, politics, judicial systems and economic situations of the countries involved, especially in relation to ensuring the free and informed consent of research subjects.

### ***Intellectual Property Rights***

27. The complex network of intellectual property laws throughout the world consists of many national, regional and international developments. In general, legal systems have been pressed to put these existing laws into service in light of recent technological advances as the development of more appropriate legal regimes has been rather slow and the proliferation of patents very rapid. The results have occasionally been problematic.

28. One of these problems involves the promotion of justice by securing the benefits of scientific and technological advances for the service of humanity as a whole. A universal instrument on bioethics can contribute to the debate on the problem within the context of an accurate understanding and guidance of (1) the international, regional and national laws on intellectual property, in particular through the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreements and (2) the practical developments involving the invocation of such laws. This issue is particularly important in relation to the human genome, as there has been an explosion in the number and scope of applications for patents. We must also keep in mind the affirmation of the Universal Declaration on the Human Genome and Human Rights (Art. 4) that *“the human genome in its natural state shall not give rise to financial gains”*, the parallel Art. 21 of the European Convention on Human Rights and Biomedicine: *“The human body and its parts shall not, as such, give rise to financial gains”* and the Advice of the IBC on the Patentability of the Human Genome (14 September 2001).

29. While intellectual property protection can provide an incentive for scientific and technological and pharmaceutical research and ensure the disclosure of the outcomes of such research to the world at large, there is a concern that premature and excessively rapid growth of intellectual property protection will impede the flourishing of free and uninhibited research, which should be encouraged at this time, when it can maximize the advantages of dramatic breakthroughs in knowledge about human biosciences. There are also important concerns about the granting of patents with unnecessarily broad terms, the parameters for the use of ‘novelty’ as a criterion of patentability, the ideal duration of patent protection, the different implications of intellectual property protection for developed and developing countries and the possibility of conflicting international rights. A universal instrument on bioethics can address these issues, harmonize possible approaches and promote international cooperation, while supporting the general idea of benefit sharing.

### ***Human Organ and Tissue Transplantation***

30. Many developments in the field of human organ and tissue transplantation give rise to many hopes and, at the same time, ethical concerns and issues requiring urgent examination and consensual action. As the advances in medical sciences and technology have continued to raise the level of successful transplantation, the need for organ and tissue donors has escalated accordingly. As a result, there has been a public effort to encourage donations, and at the same time, immense pressure to induce donors and increase the supply of transplantable organs. On the one hand, there is a strong imperative to procure organs for the purpose of providing life-saving and life-enhancing medical treatments. On the other hand, there is an

equally important need for the preservation of choice, personal liberty and human dignity, which would be offended if the disposable parts of the human body were considered commodities or bargaining tools. There is also an imperative to ensure a fair distribution of organs and tissues based on objective and transparent criteria and to avoid any discrimination (such as the exclusion of persons with a disability).

31. The following practices give rise to ethical and legal issues that need to be dealt with internationally and systematically: the use of prisoners and other individuals as sources of transplantable organs, the acquisition of organs for monetary and other valuable considerations, and the involvement of vendors, commercial agents and professionals in human organ sales. The movement of organs, donors, patients and transplant doctors across national boundaries for the purpose of circumventing domestic regulations deserves close attention. The definition and determination of death, even if the concept of cerebral death is almost universally recognized, also give rise to significant ethical concerns. The participation of non-family-related human organ donors must also be examined in light of pressures that can be applied to those who are vulnerable. In addition, the possibility of xenotransplants raises concerns about cultural values and traditions, about the nature of the relationship between human beings and other species and about the possible transmission of disease across different species.

32. Altogether, these considerations provide enough reason to contemplate both a transnational approach to policy-making and the development of practical guidelines, in order to increase the beneficial effects of life-prolonging treatment while preserving the dignity of patients and ensuring free and informed decision-making. The main road is to broaden the donations. The successful experience in countries where organ donation has been enhanced by local policies, proper organization and clear protocols can be replicated widely with the aid of a universal instrument on bioethics promoting the development of comprehensive, coordinated national strategies concerning organ and tissue procurement with the cooperation of all parties involved, and in a manner that gives due consideration to human rights, medical ethics and cultural values.

### ***The Use of Embryonic Stem Cells in Therapeutic Research***

33. As observed in the IBC Report on the Use of Embryonic Stem Cells in Therapeutic Research (2001), many scientists are convinced that embryonic stem cells bring great promise of treatment for certain diseases. These scientists argue that research on embryonic stem cells could lead to the development of transplantable tissues as therapies for a wide range of human illnesses that are currently considered difficult or impossible to treat. The motivation for working with early human cells lies, broadly speaking, in the possibility that embryonic stem cells can be used to investigate features that are specific to early human development and in their capacity to generate somatic cell types (the variety of non-reproductive cells that make up the human body). The potential benefits to human health may be huge, ranging from generating new neurons for treating patients with Parkinson's disease to learning about the molecular processes that drive the development of tumours.

34. However, the stem cells in which scientists are particularly interested are derived from the human embryo. This gives rise to the question of whether it is ethically acceptable to use cells from a human embryo (implying its destruction) in order to cultivate and investigate them in the laboratory. Although it is possible that at some future stage these cells will be used to construct part of or even entire organs for grafting into human hosts whose organs are destroyed or impaired, such cells will have been derived in the first place from embryos. Hence the ethical question: is it acceptable to create embryos or to use supernumerary embryos to derive stem cells for therapeutic purposes? A universal instrument on bioethics can draw on the conclusion of the IBC Report and take the lead in identifying an ethical framework for embryonic stem cell research that recognizes the value of cultural pluralism.

### ***Behavioural Genetics***

35. Many scientists in the field of behavioral genetics are increasingly discovering genetic and environmental influences on human behaviour. As they identify specific genes, they proceed to explore how these genes affect development in conjunction with the interaction between genes and environmental factors. Understandably, the findings have led to apprehensions about their ethical, legal and social implications. There is reason to be concerned that genetic influences on such characteristics as intelligence, memory, shyness or sociability could be exaggerated and result in the stigmatization or discrimination of individuals or groups. A universal instrument on bioethics can impress upon the scientific community the eugenic implications of generalizations that are unfounded or premature. It can also warn people about the injustice that may result either from an exaggeration of group similarities or differences, or from the denial of such features when they have actually been established. A universal instrument on bioethics can encourage geneticists to confront the issues accurately, professionally and on the basis of the best available science.

### ***Genetically Modified Organisms***

36. The use of genetic modification to address agricultural and breeding concerns has accelerated in recent years. Advocates of the technology invoke the importance of finding new ways of providing for the needs of a continually increasing world population. They have endeavoured to show how the technology can be applied to some of the specific problems of agriculture and breeding in order to expand the potential to combat pest resistance, increase yield, develop tolerance to biotic and abiotic stresses, enable the use of marginalized land, increase nutritional benefits, avoid negative environmental impact, derive pharmaceuticals and vaccines from transgenics and reduce production costs. On the other hand, some of these claims have been challenged by opponents who highlight the danger posed by unproven procedures for consumers as well as for the environment, and invoke the principle of precaution. Some have also argued for the unacceptability of transgenic procedures, which they see as a challenge to the integrity of nature, as a threat to biodiversity, or as an intrusion into what they deem to be exclusively divine prerogatives.

37. The responses of different governments have varied, and tensions exist as a result of policies that, regardless of direction, always generate controversy. The resulting situation is one that requires a global response, if only to ensure the observance of safe standards for research and consumption, as well as the promotion of equitable access to the technologies that are developed and the benefits that these generate. A universal instrument on bioethics can facilitate this response by providing an acceptable framework for understanding the various ethical positions and deliberating on a possible resolution of the concomitant conflicts.

## **V. Form and Scope of a Text on Bioethics**

38. Does the international community feel the need to set guiding principles, or indeed legislation, in such a rapidly advancing area with such wide ramifications? If so, what would be the limits of such norms and of such an institutional and regulatory framework? To what extent would the international community be able to ensure compliance with them? Could the guiding principles stand the test of time or should they be revised regularly? What would be the role of specialists, decision-makers, civil society and international organizations both inside and outside the United Nations system?

39. The affirmation that the human genome is – in a symbolic sense – “the heritage of humanity” (Art. 1 of the Universal Declaration on the Human Genome and Human Rights) means also the recognition of the human species’ unity, unique destiny and, at the same time, diversity in genes, traditions and culture. When we try to elaborate universal ethical principles we have to recognize the existence of many different ethics, in general, and bioethics, in particular. This has to be considered as an expression of human freedom rather than an obstacle. When it does not conflict with the rights of present or future generations, bioethical pluralism should be not only allowed but recognized. At the same time the universal instrument should try to stimulate the creation of a worldwide common sense in order to foster understanding and cohesion in relation to new ethical categories and new practical possibilities emerging from science and technology.

40. Moral and legal rules correspond to two distinct but interconnected orientations. Moral rules, which are set in a cultural, philosophical and religious background of the various human communities, can develop by enrichment and consensus thus contributing to common universal values. Legal rules cannot pretend to encompass all fields and cases of bioethics nor to judge or to interfere in every moment of the lives and individual choices of persons. At any level, laws accompanied by effective control should be adopted in order to facilitate personal choices, and only a few substantial issues should be regulated through international rules. In other words, the aim should be to maximize moral evolution and to minimize the need for legislation.

41. Policy-makers are increasingly confronted with issues relating to bioethics. In this domain, the debate often revolves around the level at which the legislative and regulatory framework should be placed. If the framework is too general, it may be less useful in terms of its application to specific practices. Conversely, if it is very detailed, it may be rendered obsolete by rapid advances in practices and techniques. Therefore, a balance must be struck so that normative and institutional mechanisms that are capable of standing the test of time can be introduced.

42. The term “international instrument” does not have a legally precise meaning. For the purposes of this report, it is used as a generic term that may not *a priori* anticipate the legal nature or form of a future international text. However, given that the aim of such an instrument will by its nature be *broad* and will receive *the broadest acceptance possible* by public authorities, the scientific community and the general public, the Working Group considers it preferable, in the initial stage, to settle on a declaration.

43. The tradition of international instruments on human rights is that treaties are preceded by declarations which contain guidelines and an invitation to States to follow them. This was the case with the two International Covenants of 1966 on Civil and Political Rights and on Economic, Social and Cultural Rights, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination (1965), the United Nations Convention on the Elimination of All Forms of Discrimination Against Women (1979) and the United Nations Convention on the Rights of the Child (1989).

44. However, as far as bioethics is concerned, we are presently experiencing an extraordinary and rapid development in science and technology. This must be taken into account when establishing an international declaration of such scope. Moreover, the term “*universal*” should be avoided at that stage. In any event, the instrument will need to be re-examined and eventually revised at regular intervals.

45. The form of the instrument does not prevent its content from contributing to a code of universally recognized general principles of bioethics (such as human dignity, solidarity, freedom of research, autonomy, respect for privacy, confidentiality, non-discrimination, informed consent, integrity of research and intellectual honesty) insofar as these principles pertain to bioethics.

46. The declaration will no doubt contribute to a strengthening of the role and the degree of participation of ethics committees at national and institutional levels: those that are designated by laws or regulations to authorize medical interventions or scientific research and to evaluate the results achieved. The national committees or similar bodies that exist or are being created in many countries represent a rich variety of cultures and experiences; they can be harnessed as an international forum in the preparation of the declaration and in the implementation of its recommendations.

## **VI. Education, Information, Awareness-Raising and Public Debate**

47. A universal instrument on bioethics must call strong attention to the importance of awareness-raising, information, education, consultation and public debate in accordance with Art. 23 of the Universal Declaration on the Human Genome and Human Rights: “*States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.*” These activities are essential and fundamental to the pursuit of all research in this field in a spirit of solidarity, humanity, reason and harmony. Harmony can only exist if fears, hopes and questions are taken into account in the drafting of public policies, laws and regulations. This means that the processes of elaboration and implementation of scientific applications must be accompanied by an ongoing, more accessible and transparent public debate that is open to the lay public and covers both the potential benefits and the hazards of scientific applications.

48. These concerns form part of the fundamental mission of UNESCO, whose features include promoting the dissemination of and access to knowledge and serving as an intellectual forum for reflection and dialogue. Articles of the Universal Declaration on the Human Genome and Human Rights (in particular, Articles 20, 21, 22 and 23) deal with this subject and appeal to Member States to promote education and training. The same appeal is made in the Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights, which was endorsed in 1999 by the General Conference of UNESCO at its 30th session.

49. The statements and ideas put forward to the Round Table of Ministers of Science on “Bioethics: International Implications” (Paris, 22-23 October 2001) at the 32nd Session of the General Conference point in the same direction. Reference was consistently made to the importance of education; the provision of adequate information to healthcare professionals, schoolchildren and students, politicians and civil servants; the training of specialists in genetic counselling and bioethics; and the ongoing training of ethical committees in hospitals, research centres and other institutions.

50. The Communiqué adopted by the participants in the Round Table provided that “*governments of Member States and legislators ... must see to it that citizens have an opportunity for informed, pluralistic public debate, and must take into account the various schools of thought, value systems, historical and cultural backgrounds, and philosophical and religious convictions that make up our various societies*”, clearly meaning that “*bioethics must be based on the practice of democracy and the active participation of all citizens*”.

51. In areas such as genomics research, prenatal diagnosis and population genetic studies, it is becoming increasingly important for ethical, legal, psychological and social reasons that all the individuals and groups concerned (in particular healthcare professionals) be kept informed and trained.

52. In light of all these considerations, UNESCO can take advantage of the opportunity provided by a declaration on bioethics to encourage Member States to set up national and regional bodies designed to encourage the population to take part in informed debate in various fields, including those related to the most recent developments in biotechnology that are liable to affect them. UNESCO can also take the opportunity to encourage Member States to involve their scientific community, universities and other academic centres, the media, non-governmental organizations, politicians and civil servants in this dialogue; to promote the active participation of everyone affected by these issues; to provide the means for all citizens to receive clear and precise information on the impact of the procedures available; to ensure that populations can give truly free and informed consent in every circumstance or, if they so wish, decline such procedures; and to publish reports on the agencies and activities that have been put in place to promote bioethics education in their countries.

## **VII. Conclusion and Recommendations**

53. The initiative of the Director-General of UNESCO in favour of a universal instrument on bioethics deserves support. The UNESCO IBC accepts the challenge of elaborating an international instrument on bioethics. That would serve the interests of the international community as a whole, and of disadvantaged people in particular.

54. The UNESCO-IBC recommends that the instrument be a declaration. Such an instrument can leave the door open for subsequent protocols when the need for more definitive norms becomes necessary and timely. A declaration can also provide for a reporting mechanism that will enable Member States to monitor the extent to which they have given their support and provide the UNESCO with the pertinent information.

55. The instrument could focus on the basic principles of bioethics without ruling out the option to provide specific guidance where it would be compatible with respect for the cultural pluralism that UNESCO also seeks to promote. The Universal Declaration on the Human Genome and Human Rights is itself limited in scope, as it applies only to the human genome. At the same time it a) specifically mentions examples contrary to human dignity, such as the reproductive cloning of human beings (Art. 11) and germ-line interventions (Art. 24); b) underlines the role of the UNESCO IBC in identifying practices contrary to human dignity; and c) sets forth distinct principles on ethical values that should be considered in the international instrument, such as prior, free and informed consent, no financial gain, confidentiality, non discrimination and solidarity.

56. UNESCO should assume a leadership role in the preparation and negotiation of such an instrument. For this purpose it will be useful for UNESCO to obtain a clear mandate from its General Conference in order to avoid duplication, confusion and conflict of prerogatives with other institutions. UNESCO should work in conjunction with other bodies of the United Nations such as the World Health Organization, the High Commissioner for Human Rights, the Food and Agricultural Organization, the International Labour Organization, the World Trade Organization and the World Intellectual Property Organization. It should also consult national bioethics bodies, civil society and all other groups that could be affected by the promulgation of such an instrument.

**COMPOSITION OF THE IBC WORKING GROUP ON  
THE POSSIBILITY OF ELABORATING A UNIVERSAL INSTRUMENT ON BIOETHICS**

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