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**RESULTS OF THE WRITTEN CONSULTATION ON
THE THIRD OUTLINE OF THE TEXT OF A DECLARATION
ON UNIVERSAL NORMS ON BIOETHICS (27 AUGUST 2004)**

In response to the written consultation carried out between October and December 2004 on the Third Outline of the text of a Declaration on Universal Norms on Bioethics (27 August 2004), as of 7 January 2005, the Secretariat had received twenty-seven contributions from Member States and one response from a Permanent Observer, four contributions from intergovernmental organizations, fourteen from non-governmental organizations, and institutes, thirteen contributions from national bioethics committees and ten contributions in a personal capacity.

It should be noted that the results of the consultation were brought to the attention of the Drafting Group of the International Bioethics Committee (IBC) which, at its sixth meeting (Paris 12-14 December 2004), finalized the Fourth Outline (15 December 2004).

The contributions are presented in this document in **five** parts.

Part I presents the comments received from Members States and Permanent Observers to UNESCO. The contributions are provided in English and in French.

Part II presents the comments received from intergovernmental organizations. In this regard it should be noted that on the occasion of the fourth meeting of the UN Inter-Agency Committee on Bioethics (Paris, 10 December 2004), Members and Associate Members of this Committee had an opportunity to have an exchange of views with the members of the IBC Drafting Group on the Third Outline. Further observations and comments were formulated by the participating organizations during the fourth meeting of the Committee.

Part III presents the comments received from non-governmental organizations, Part IV comments from national bioethics committees and similar bodies and Part V contributions submitted in a personal capacity.

Partie / Part I

ETATS MEMBRES/MEMBER STATES

- *Allemagne / Germany*
- *Autriche / Austria*
- *Belgique / Belgium*
- *Bolivie / Bolivia*
- *Brésil / Brazil*
- *Canada*
- *Danemark / Denmark*
- *Equateur / Ecuador*
- *Etats-Unis d'Amérique / United States of America*
- *Finlande / Finland*
- *France*
- *Inde / India*
- *Indonésie / Indonesia*
- *Jordanie / Jordan*
- *Japon / Japan*
- *Lesotho*
- *Mexique / Mexico*
- *Monaco*
- *Norvège / Norway*
- *Paraguay*
- *Pays-Bas / The Netherlands*
- *Portugal*
- *Roumanie / Rumania*
- *Sénégal / Senegal*
- *Suède / Sweden*
- *Suisse / Switzerland*
- *Turquie / Turkey*

Permanent Observer: *Saint Siège / Holy See*

GENERAL COMMENTS

Allemagne/Germany

Germany supports the elaboration of a UNESCO Declaration on Bioethics and is willing to play a constructive role in next year's negotiations. Our goal is the elaboration of a high quality text which, in so far as possible, should be completed by 2005, the deadline set by the 32nd session of the UNESCO General Conference and approved by the Executive Board.

As regards the options set out in the UNESCO letter of 11 October 2004, Germany favours option A (general principles, with concrete subjects to be dealt with in future/subsequent texts).

The principles must not fall short of European standards and those found in the UNESCO Declarations on the Human Genome and on Human Genetic Data. New developments in international law should also be taken into account. In particular, the three fundamental principles found in Articles 1, 2 and 3 of part II of the Treaty establishing a Constitution for Europe (protection of human dignity, right to life, right to the integrity of the person) must be guaranteed. Regional conventions such as 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 must also be given appropriate consideration.

Further principles, such as the right to life and responsibility for future generations, should be included or expanded in the text of the Declaration.

The classification of certain principles as "fundamental" or "derived" needs further revision.

One of the greatest challenges will be defining the scope of the Declaration. This will depend on a well-formulated compromise being found that satisfies those States which wish to include biodiversity and the biosphere in the Declaration and those which want it to be strictly limited to human beings.

Article 2 in conjunction with Article 25 of the Declaration imposes a duty on the Member States. They are to give effect to the fundamental and procedural principles through legislative and other measures and so create a framework for the activities of individual researchers, groups and institutions. A number of the individual principles, as presently formulated, could however be understood as constituting direct instructions to individual researchers or doctors. It would be worth considering whether it would be more appropriate to formulate individual principles as general principles, or whether a formulation should be adopted that expressly addresses the Member States.

Autriche/Austria

In the present version objective and scope of the project are not sufficiently clear. The precise meaning of the expression "bioethics" for the purposes of the Declaration at hand would need to be clarified. This includes the question to what extent other forms of life are to be protected in addition to human beings and what issues relating to mankind are to be covered.

In this regard, Austria wishes to remark that vague terms (e.g. "human dignity") should be avoided. All language used in the text of the Declaration should be standardized and used consistently.

Also the question arises to what extent provisions regarding the "Sharing of Benefits" (Art. 13) or "Solidarity and International Cooperation" (Art. 24) are to be treated in the specific context of bioethics as proposed.

Work on the future declaration should focus on elaborating a text that proclaims general principles in the field of bioethics with concrete subjects to be dealt with in other texts.

Furthermore – and bearing in mind that a "declaration on norms" could be considered a contradiction in terms – Austria would like to remark that the term "norms" should be avoided in the title as it would be misleading, taking into account the non-normative nature of a declaration. This also applies to the use of the term "shall" – which should be replaced by "should" throughout the text – as well as to the proposed monitoring mechanism. It is difficult to conceive that the application of a non-binding document would be monitored.

The expression “international human rights law” should replace the varying present wordings in this draft for the sake of consistency.

Also, the term “humanity” appears somewhat complex for the purposes of the present draft declaration and should be replaced by an expression like “human being”. This term should then be used consistently in the whole text.

It appears preferable not to repeat the requirement that bioethical issues must be in compliance with existing international obligations, but to lay down such a requirement at the beginning in a single horizontal provision that applies to the whole text.

By the same token a definition of the term “human dignity” could be endeavoured in a horizontal provision – apart from enshrining it as such, as is done in Article 3 of the draft.

Finally Austria is of the opinion that the present draft clearly shows that in the light of the interdependence of the individual concerns, a systematic set-up including a division into various categories of principles can hardly be achieved. The proposed division should therefore be dropped.

Belgique/Belgium

While it is pleased that some of its earlier remarks have been taken into account, Belgium believes that the third outline is still hard to read with regard both to the text as a whole and the individual provisions. It suggests a simpler structure, organized as follows: General Provisions, Principles, Procedures.

Brésil/Brazil

The draft text is well developed with regard to the provisions on the protection of civil and political human rights. However, it is too narrow in scope in relation to the development of aspects connected to economic, social and cultural rights, which represent the “social agenda” of the draft declaration. The risk is that the original intention of drafting a universal declaration on the theme of bioethics will give way to a partial, limited and selective approach to the theme.

As it stands, the text, in response to obligations that are international as well as political and moral in nature, places the developed and developing countries on an equal footing. Yet, it is in the developing countries that we find populations and individuals who enjoy the fewest rights to health care, who are the most affected by the absence of health care and access to high-quality drugs, by illegal practices like biopiracy and by criminal practices like organ trafficking or the illegal sampling of genetic material and human tissue. It would thus be preferable to include in the text a clear definition of States' obligations in the field of international cooperation, regular access to scientific research and technological progress, and the fostering of mechanisms for capacity-building, research and development run jointly by the developed and developing countries as well as for the transfer of technology, based on the principal of reciprocity.

Canada

In general, good progress is being made on the development of the Declaration, and the drafting group is congratulated for its hard work. The Scope and Aims of the Declaration are of such significance that it is recommended that these become primary headings, as opposed to their current treatment as subsidiary headings under the current General Provisions heading. The General Provisions heading should be removed, as a result.

Further, the distinction between General [Fundamental] Principles and Derived Principles is questioned. While the concept of fundamental and Derived principles may be useful in academic ethical analysis, it is unclear that it is useful in a document that is intended to provide guidance to States, particularly with respect to conduct that impacts on the human rights of their citizens. Many of the problems of drafting associated with the statements of General Principles arise from the attempt to elevate the expression of these principles to a level of generality that renders them unclear and uncertain in their application. Consideration should be given to doing away with the distinction between fundamental and Derived

principles, and an effort made to express these principles in a fashion that makes clearer their application between the State and the individual.

As the proposed document is to be a non-binding Declaration, it is generally not acceptable to use the term “shall” when discussing recommendations for State or individual conduct under the document. The use of the term “should” is more appropriate. The use of the term “shall” is appropriate, however, where the provision refers to existing rights and obligations without modifying them, such as “States shall respect international human rights law and principles”.

Care needs to be taken to adopt consistent terminology to express the same idea throughout the document. Examples of inconsistency include:

- the many references to human rights need to be made consistent. The preferred expression is “international human rights law”;
- the principles are described, variously, as the principles, a universal framework of fundamental principles and basic procedures, a framework of ethical principles, the universal principles, etc.

It is recommended that consideration be given to having the Declaration incorporate, by specific reference, existing international provisions pertaining to a number of relevant issues, including: the right to found a family, the right to benefit from scientific progress and its applications, and freedom of research. It is also recommended that the principles address the issue of commercialization of the human body and its parts and the need to protect the integrity of the human genome. It may also be desirable to include a principle addressing the need to take appropriate measures to protect vulnerable individuals and vulnerable populations.

Danemark/Denmark

Denmark finds that the Third Outline of a Text of the Declaration on Universal Norms on Bioethics is of a very high standard. It reflects a very thorough and balanced approach to the issues concerned. The Declaration focuses primarily on the human being but with due recognition of the duties and responsibilities towards the biosphere and with affirmation to the need to deal with all the aspects of the biosphere through the elaboration of guidelines and international instruments on ethical principles related to the environment and other living organisms. In that context Denmark would like to draw the attention to the fact that other international organizations are preparing or have prepared instruments, which include the same objectives and scopes as the proposal from UNESCO. Therefore, it is important that UNESCO in the further development is aware of the necessity to ensure concordant universal guidelines.

The Declaration sets out the principles with a distinction between general principles, derived principles, procedural principles, and procedures. Denmark supports the elaboration of a text that proclaims general principles in the field of bioethics (option 1) and supports a declaration without “specific issues” as foreseen in this third outline of the text.

The risk issues

A glance at the last 10 years’ debate on biotechnology readily reveals that the risk aspect occupies a prominent position. A large part of the social conflicts played out around biotechnologies seemingly deal with these technologies’ inherent potential for danger. How will these technologies affect our health and welfare, our social and cultural identity and the environment? Moreover, what precautions should society take to minimize or altogether eliminate these risks?

Such scientific risk assessments have acquired ever greater significance for societal decisions within modern biotechnology. At the same time, however, criticism has been raised in the public services of these assessments’ inadequacy – criticism largely concerning the fact that scientific risk assessments have a tendency to treat risk as a neutral and objective dimension. Risk is not just a question of science but also of values, see below.

Firstly, scientific risk assessment involves a number of built-in choices of problems, methods and descriptions. These choices can be both well founded and necessary so that the risk assessment taken as a whole can provide a result that can be incorporated in an institutional

context but they are never value-free and neutral. Secondly, there is a limit to the risk assessment's predication, that is to say the relationship to reality on which it can meaningfully pronounce. Scientific risk assessment has a tendency to include hard and quantifiable aspects and conversely to preclude soft and qualitative aspects of the risk concept. To understand the conflicts of "risk society" it is necessary to adopt a broad, social concept of risk. This must include risk as it is perceived and construed by different individuals and cultures, and must recognize that the conflict between different interpretations and constructs of risks make a fundamental condition for policy-making. A concept that does not reduce the risk to numbers and probabilities but also sees it as a question of social learning processes and communication.

The precautionary principle thus permits rejection when insufficient scientific certainty exists to vouchsafe the safety of the product. However, it is far from given that the precautionary principle would cover a situation in which there was no question of scientific uncertainty, but rather a move to reject a product on other (ethical) grounds. If a situation regarding human health is considered – e.g. human cloning – it is then possible to take into account the view that has dominated the debate (certainly in the Western World), namely that "this is unacceptable under any circumstances". This attitude is informed by an altogether different premise from that of scientific risk assessment. In other words, if the pivotal question is: "Is it *safe* for humankind and nature?" there will be no room left for the ethical dimension: "Is it *right* for humankind and nature?"

Involvement of the younger generations in public debate

Denmark would like to stress the need for generating public debate and dialogue. We suggest that this be mentioned in the appropriate article on implementation, which already mentions education and training. Debate and dialogue are measures that necessitate a two-way communication, whereas education and training only is one-way. Moreover, we want to specifically stress the need for involvement of the younger generations in bioethical issues. The younger generations are going to live with the decisions made nationwide and worldwide regarding bioethical questions hence the Declaration's obligation to address this issue.

Equateur/Ecuador

Ecuador believes that the Declaration is especially important for peoples who are affected daily by industrialization. Serious consequences can result from a non-rational exploitation of oil, that is, when there is a failure to take adequate steps to prevent the harm that may be done to hundreds of thousands of individuals (skin diseases, blindness, cancer). Some indigenous communities in the Ecuadorian Amazon, whose very survival is at risk, have called for immediate action to be taken to deal with that phenomenon. The problem directly affects not only human beings but also the flora and fauna, since rivers are being contaminated every day. If we fail today to protect the "lungs" of our planet, tomorrow we will be mourning their extinction. Another serious problem is the use of genetically modified products by consumers who are not warned about the possible consequences. Ecuador is confident that the Declaration can facilitate and open the doors to the use of generic drugs and close them to all trafficking in human organs.

Etats-Unis d'Amérique/United States of America

The United States Government (USG) supports the advancement of knowledge, standards and intellectual cooperation to help facilitate social transformations in which the values of justice, freedom and human dignity can be fully realized. In this context, we support a Declaration on Universal Norms on Bioethics that would serve as a useful guide to developing and developed countries alike as they build the necessary capacity and competency to address the range of complex issues surrounding the area of bioethics.

Purpose: Properly framed, a Declaration should provide a framework of fundamental principles to guide Member States in the formulation of legislation and policies in the field of bioethics and to inform entities and individuals that develop guidelines in bioethical matters. The Declaration should capture the concept of recognizing and promoting further understanding of the benefits and risks that could derive from scientific and technological development, while ensuring that such development occurs in accordance with bioethical principles that respect humanity and human dignity and are not inconsistent with human rights and fundamental freedoms.

Such principles include human dignity, freedom and integrity of research, respect for privacy, confidentiality, non-discrimination, informed consent, and intellectual honesty. Other principles relevant for all Member States include access to information and exchange of information, evidence-based policy development, ensuring research involving human subjects is ethical and transparent, and capacity-building in-country, including national bioethics committees and review boards.

Relevance to Member States: To earn wide support from Member States, a Declaration should identify elements that are flexible enough so as to remain valid and meaningful over time within the expanding field of bioethics; raise awareness of the important role of bioethics both within countries and across borders; and guide countries in their efforts to support relevant and practical bioethical principles, as well as build the national capacity needed to effectively develop and implement such principles.

In upholding bioethical principles, there is often a need to counterbalance competing ethical norms. As such, the language of the Declaration must maintain the strength of the commitment to fundamental principles while concurrently acknowledging that in practice these principles require reflection and a balancing of the relevant ethical demands. For example, the primacy of the human person is an important and fundamental concern, deriving from basic human rights and respect for human life, dignity and autonomy. However, there are also times when the protection of the public health and safety might need to take precedence over the rights of individuals. Societal decisions such as these must be made with great care and deliberation; in fact, they are the subject of extensive debate in literature on public health ethics and human rights. If the Declaration is to have validity and credibility among the diverse Member States, the drafters will have to achieve a greater complexity and nuance in articulating the basic principles, each of which are, in practice, complicated by their interrelationship with other important moral concerns.

Scope: The UNESCO Declaration should contain general principles that help to frame the ethical, legal, and cultural dimensions of medical and life sciences and their associated technologies as they affect human beings, again by using a foundation that promotes respect for human life and dignity and the protection of human rights and fundamental freedoms. The Declaration should advance the application of existing knowledge and standards in these areas.

Focus on humans: The Declaration should focus on humans. In order to be meaningful, achievable, and effective, the Declaration should further focus on medical and biological issues relating to human beings and human health.

Non-duplication: A number of international organizations, including other United Nations (UN) agencies, engage in ongoing global policy debates and provide technical and scientific guidance under the broad rubric of bioethics. These include the World Health Organization (organ/tissue transplantation, research involving human subjects, access to medicines, biomedical research, and access to health care), the World Intellectual Property Organization (intellectual property rights), the World Medical Association, and the Codex Alimentarius Commission (international trade in food and food/nutritional labeling), to name only a few. In addition, the United Nations General Assembly's Sixth Committee began a third year of debate on human cloning this fall, which will continue in 2005.

Any proposed UNESCO Declaration should draw on the information and data that emanate from these venues without duplicating the work done in these current initiatives and without competing with these organizations' recognized and long-standing leadership, mandates, and competencies in these areas of bioethics.

Consensus: This Declaration should not include issues where the leaders of the international scientific and ethics communities have yet to reach consensus. These include areas such as research involving human embryonic stem cells, gene therapy research, and genetically modified organisms. Without a better understanding of the range and complexity of the issues and their associated risks and benefits, attempting to include norms on such issues within a Declaration at this time is premature.

The United States looks forward to working with Member States on a Declaration that will have meaning and relevance at the national and international levels and contribute to the expanding principles that cut across a range of issues related to bioethics.

Finlande/Finland

It is essential that the declaration mainly focuses on compiling bioethical principles relating to the human being. The process of compiling ethical principles concerning the biosphere at large would be too massive a task. Interventions concerning the human being are also an area where ethical principles are acknowledged into the largest extent. This means that the draft declaration of the narrower scope will have better chances of being practicable. Principles relating to health care in general, scientific research, animals, plants and biodiversity could be compiled into separate declarations, recommendations and corresponding instruments, if the UNESCO Member States so wish.

The basic structure of the declaration (General/Fundamental Principles, Derived Principles, Procedural Principles, Procedures, and Promotion and Implementation) is logical. The Drafting Group has put forward two alternative outlines: 1) to limit the Declaration to the level of principles or 2) to include detailed provisions concerning health care and scientific research under “Specific Issues”. Finland considers the first alternative better. This would enable the Declaration to concentrate purely on determining the ethical principles which apply to human beings without going into detail in other areas. By approaching the issue at a general rather than detailed level, the Declaration will also keep its relevance in the longer run under changing circumstances.

The term “human being” will probably prove to be too difficult to define because it would lead to questions about the point at which human life starts and to the suggestion that the term would cover life from conception.

The draft Declaration systematically uses the terms “decisions or practices” and it is for the reader to guess what they mean. Do they include, apart from medical treatment and examination decision, also other kinds of decisions concerning treatment and examination, binding norms, administrative decisions or all practical action?

France

Generally speaking, our reply to the survey carried out last spring remains valid, in particular with regard to certain aspects of the outline that are still in contradiction with the views we expressed at that time: France believed in particular that the Declaration should be limited to human beings, should refer to specific subjects and should link bioethics and human rights even more closely.

The current distinction made in the outline between fundamental principles, derived principles and procedural principles is not clear. At the very least, that distinction should be explained more clearly. Several of the principles included under the heading “Derived Principles” appear to us to be fundamental. For example, can the primacy of the human person really be regarded as a derived principle?

Indonésie/Indonesia

The Third Outline of the Declaration on universal norms on bioethics was circulated for comments since October 2004, has already taken its shape. We consider it to be balanced. We take special note of the coverage of the Declaration. We do not consider that a too-narrow formulation is valuable, practical nor necessary, even under the urgency of the matter we are witnessing in the world today for example in the issue of stem cell research.

We need a wide spectrum of topics associated with bioethical norms, as these will be at the core of a range of our future decisions in the varied real-life situations. This is the source of well-designed guidelines for all parties in the course of the development of the life sciences. It is also important to have these topics within an organized and structured information body, which will be crucial for decision-makers at every level within the community at large – in scientific research, technological development and implementation. Our preference is for a comprehensive approach; not only do we include non-human aspects of bioethics, but rather, more importantly, we consider living organisms as an interconnected global system of intricate inter-reliant systems of life. This is the context of the human dignity and the integrity of the human species.

Monaco

The question may be raised as to whether the heading “Procedural Principles” should be maintained. The two terms would appear to be incompatible. Procedures imply a practical side which has nothing to do with principles. We suggest that the section be included under “Derived Principles”.

Norvège/Norway

The text of the declaration is quite general; we consider that necessary as the bioethical standards in each Member State must be based on the cultural and religious standards of that particular state. However, respect for human rights, human dignity, and cultural and biological diversity must be balanced against cultural and religious standards.

The text does not discuss some of the most burning issues within bioethics, for instance,

- when does life begin?
- what is a human being?
- economic interests
- genetic material from indigenous peoples
- ethical dilemmas between rich and poor nations

The text should contain a paragraph which forbids trade in human organs and the cloning of human beings. A definition of terms should be annexed. All Member States should be encouraged to establish national ethics committees.

Paraguay

The Declaration has left out or has yet to include themes closely tied to bioethics, such as access to health care and drugs and the right to a life of dignity and a healthy environment, as well as respect for biodiversity and refusal of environmental contamination, essential for a good quality of life. A declaration cannot be universal if it leaves out these and other problems which affect perhaps the majority of the world’s population, who are faced with poverty, hunger, illness, social exclusion and, in many cases, violence, especially as it is composed of vulnerable groups such as children, the elderly, persons with disabilities and the surviving indigenous populations in Latin America. For the reasons just expressed, and in light of the discussions at the regional seminar on bioethics, sponsored by UNESCO and held on 4 and 5 November 2004 in Buenos Aires, we ask that the Declaration not be approved until it gives expression to the concerns of all countries, including these and other macrobioethics issues.

Pays-Bas/The Netherlands

The distinction between “general/fundamental principles” and “derived principles” needs further clarification. Do we need the term “derived principles”?

The expression “any decision or practice” included in various articles seems to be very wide. It may be helpful to provide examples of decisions and practices that are borderline cases, to illustrate and clarify the scope of the instrument.

Due to the nature of a declaration as a non-binding instrument, the word “shall” has to be replaced by “should”.

Roumanie/Romania

In view of the rapid progress in science, research and biotechnology, which is not always predictable, we suggest that it be stipulated in the Declaration that its text may be amended as necessary.

We should like to point out that religious doctrines and philosophies have been developed over centuries and millennia and are generally unchanging. It is therefore difficult to use such doctrines to interpret and adapt the new discoveries about living beings.

We should like to propose that the Declaration lay emphasis on values and concepts that are specific to particular cultures such as, for example, “common good”, “collective good” and “values and ethics of the family”, to achieve a balance with the ideas of “individual good” and

“ethics of the individual” developed in the European and western cultures (North America, Australia).

The Declaration should stress the expansion of bioethics (beyond human beings who remain, however, the central axis) to the biosphere as a whole, as we know that human beings can only flourish in the context of a safe, protected and well-defended biosphere.

With regard to family relations, while the obligations of parents to their children remain a priority, emphasis should also be placed on the obligations of children to their parents, which should be part of a broader family and social ethic.

Suède/Sweden

The declaration makes a difference between general and derived principles (Articles 3-7 and 8-13, respectively). It is not obvious, however, how the latter principles are derived from the former. Nor is it obvious from which principles they are derived. A clarification would be useful.

Turquie/Turkey

The draft text (27 August 2004), as it stands, has two main components: one is the part on principles (fundamental, derived and procedural) and the other on procedures of their application. The first part codifies existing relevant principles. The second part formulates procedures concerning the application of these principles by States and the international community. The second part makes a substantial contribution to this field, though lack of reference to the precautionary principle under procedural principles may create an obstacle for the attainment of the aims of drafting such a Declaration, for example in certain cases undermines the principle of the primacy of the human being.

The Declaration must recommend “Risk Management” in connection with the precautionary principle, as a necessary method complementing it for its application, because it is a decision-making strategy essentially designed for the private sector and suggested for public services. The Declaration must recommend the application of the “Precautionary Principle”, particularly in relation, not only, but mainly, to human health. This principle asserts, among other things, that the burden of proof for potentially harmful actions by industry or governments rests on the assurance of safety and that when there are threats of serious damage, scientific uncertainty must be resolved in favour of prevention. This is an ethical principle applied in many developed countries in all fields involving risks to human health and safety as part of the general policy-making. Otherwise, the Declaration can even be counter-productive.

The declaration must include the ethical responsibilities of the international business community active in this field, as they are among the main actors. Many articles of the draft Declaration, especially the wording of the risk management, implicitly meet the concerns of the business community. Therefore, their responsibilities should also be specified in the declaration with an article as follows:

“Article...- Responsibilities of the Business Community

The business community, in particular the sectors related to the issues of the present Declaration, should take all appropriate measures to give effect to the principles and procedures set therein, in accordance with the Global Compact.”

It is the sovereign right of a State to authorize and regulate scientific research carried out on its territory. The Declaration should emphasize that international scientific research must be carried out only with the express consent of the State where the research will take place and also its conduct must be based on bilateral or multilateral agreements that also define benefit sharing, technology transfer, conditions of the ethical review and other requirements of compensatory nature aiming to protect the interests of the developing countries. Furthermore, IBC may be charged to be the watchtower for the proper application of the international scientific research articles of the Declaration, as “competent international organization of scientific research involving bioethical issues”.

More emphasis should be put on education of bioethics and also on the need of basing it on philosophical ethics, so that those trained can develop the sincere will to protect human dignity and become able to find its implications in given cases.

TITLE

AUTRICHE/ AUSTRIA	“Universal Declaration on Bioethics and Human Beings”
BELGIQUE/ BELGIUM	“Universal Declaration on Bioethics [and Humankind]”
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Universal Declaration on Bioethics” Even though the 32nd General Conference (GC) resolution calls for a “Declaration on Universal Norms on Bioethics”, the term “universal norms” is of concern as there is no global consensus around such norms at this point in time and reaching consensus on what such universal norms would encompass would be impossible to attain in this type of declaration.
FINLANDE/ FINLAND	“Universal Declaration on Bioethics and Human Beings”
FRANCE	France would like to maintain in the title the words “Universal Norms” which, in its view, are more meaningful than a simple declaration on bioethics.
JORDANIE/ JORDAN	“Declaration on Universal Norms on Bioethics”
MEXIQUE/ MEXICO	“Declaration on Universal Norms on Bioethics”. We have chosen this title because the concept of “bioethics” encompasses, by definition, ethical concerns regarding scientific progress in the field of biology and, consequently, its relationship with human values. With regard to the text in square brackets, in addition to considering it unnecessary, we believe that the term “human beings” could give rise to problems in the negotiations, as has happened in other contexts (cloning).
PAYS-BAS/ THE NETHERLANDS	“Declaration on Universal Norms on Bioethics”
PORTUGAL	“Universal Declaration on Bioethics and Human Beings”
ROUMANIE/ ROMANIA	The word “universal” seems to us appropriate, given the precedent already accepted with regard to the Universal Declaration of Human Rights and fundamental freedoms. The word does not lay down a binding obligation but simply implies broad acceptance. With regard to including or maintaining the word “norms”, we believe that the word could be omitted because it has different meanings in different languages.
SUÈDE/ SWEDEN	“Universal Declaration on Bioethics”
SUISSE/ SWITZERLAND	“Declaration on Universal Norms on Bioethics”
SAINT SIÈGE/ HOLY SEE	“Declaration on Universal Norms on Bioethics”

PREAMBLE

AUTRICHE/ AUSTRIA	Austria suggests listing only the core international human rights documents with a catch-all phrase for others in such a way as to also encompass regional documents and possible further documents.
CANADA	The Declaration should have a preamble, but consideration should be given to shortening it, in order to improve the reader’s understanding of the document. 1. The first paragraph should refer to the most relevant international human rights instruments, in order to give primacy to the application of human rights. The international instruments that should be referred to would include the <i>Universal Declaration on Human Rights</i> and the <i>International Covenant on Economic, Social and Cultural Rights</i> . For the sake of conciseness, the paragraph could conclude with a general reference to “other relevant international human rights instruments”. 2. The current first paragraph could become the second and remain unchanged. This would accord an appropriate priority to the current UNESCO Declarations. Typically, Declarations are recited in separate paragraphs from binding Conventions. 3. The third paragraph could then refer to the Convention on Biological Diversity and TRIPS, and it could conclude with a general reference to “other relevant international” instruments”. These two conventions are relevant, but they are not human rights instruments. Hence, the need for a separate paragraph.

	<p>4. The fifth, sixth and seventh paragraphs could either be shortened and combined into one or removed entirely. They serve to justify why UNESCO is developing the Declaration, and the need for this in the document is questionable.</p> <p>5. The balance of the Preamble seems generally all right.</p>
FRANCE	France welcomes the mention in the preamble of the 1997 Convention of the Council of Europe and other regional instruments in the field of bioethics. Furthermore, the references to the major human rights texts serve to focus the Declaration on its essential aim – the protection of the human person in the light of developments in biology.
PAYS BAS/ THE NETHERLANDS	Would it be advisable to include the United Nations Convention Against Torture? It could be useful to consider the relation of the tenth preambular paragraph with Article 5. The wording of the latter seems stronger.
SUISSE/ SWITZERLAND	In the paragraph stressing the benefits of scientific progress, it would be useful to mention also the shared challenge arising from the problems engendered by that same progress.

TEXTUAL PROPOSALS

BELGIQUE/ BELGIUM	<p>Also recalling the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, as well as the other international and regional instruments, national legislation and regulations in the field of bioethics,</p> <p>...</p> <p><u>Considering</u> that, by virtue of its Constitution, it is incumbent upon UNESCO to promote “the democratic principles of the dignity, equality and mutual respect of men:” and to reject any “doctrine of the inequality of men and races”, and that this constitutes a saered duty which all the nations must fulfil in a spirit of mutual assistance,”</p>
BOLIVIE/ BOLIVIA	<p>“<i>The General Conference,</i></p> <p>Placing emphasis on:</p> <p>- The Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003, Also recalling the Universal Declaration of Human Rights of 10 December 1948, the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Recommendation of UNESCO on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement and Public Health of 14 November 2001-</p> <p>- The established standard-setting corpus and the other international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system, Also recalling the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, as well as the other international and regional instruments, international and national legislation and regulations in the field of bioethics, and Also recalling the international and regional codes of conduct, and guidelines and other ethical texts in the field of science and technology,</p> <p>Considering:</p> <p>That the <i>raison d’être</i> of bioethics is life, the supreme value to be defended, preserved</p>

and strengthened, respecting the quality and essence of humankind, in an existential context of interdependency with the biosphere and the other living species which, in their turn, must be respected, based on regulations that maintain an overall healthy ecological balance,

That human beings, recognized as the highest and most intelligent manifestation of our planet, have unavoidable responsibilities and duties towards other forms of life, confronting in an active and participatory manner damage to nature and its biodiversity, such as the indiscriminate hunting of animals, degradation of forests and deforestation, desertification, contamination of the environment and water, and alteration of ecosystems.

~~Bearing in mind~~ UNESCO's activities and programmes in the field of natural, social and human sciences, aiming at placing scientific and technological development in a context of ethical reflection, and at promoting the sustainable use and conservation of biological diversity and the improvement of the relationship between human beings and ~~their environment~~ **their specific environments,**

~~Considering also~~ That it is the mission of UNESCO to develop universal principles and norms based on shared values **of humankind** in order to meet the challenges of scientific and technological development, ~~and social transformation, in order to meet emerging challenges in science~~ taking into account **the obligations and** the responsibility of the present towards future generations,

~~Considering~~ That, by virtue of its Constitution, it is incumbent upon UNESCO to promote "the democratic principles of the dignity, equality and mutual respect of men" and to reject any "doctrine of the inequality of men and races", and that this constitutes a sacred duty which all the nations must fulfil in a spirit of mutual assistance,

That in light of the foregoing, UNESCO repudiates and expresses its profound concern about damage to the life, dignity and rights of human beings, for example, war, and violence in all its forms, injustice, exclusion, corruption and other evils which, in turn, give rise to illness, hunger and poverty in a growing share of humanity,

That in the face of such evils we have a moral and material obligation to unite to promote and establish as soon as possible a new ethic of human survival,

~~Aware that human beings are an integral part of the biosphere and that they have responsibilities and duties towards other forms of life,~~

~~Recognizing that scientific and technological developments~~ **The significant and positive fact that scientific and technological development has** been of great benefit to humankind in increasing *inter alia* life expectancy and improving quality of life and emphasizing that such developments should always promote the welfare of individuals and humankind as a whole in the recognition of the inherent dignity of the human person and the universal respect for, and observance of human rights and fundamental freedoms,

~~Bearing in mind that, without prejudice to the universal respect for, and observance of~~ **Noting, nevertheless, that such development should always be guided by due respect for the dignity and essence of human beings, human rights and fundamental freedoms; cultural diversity, as a source of exchange, innovation and creativity, is necessary for humankind and, in this sense, it is the common heritage of humanity, and should aim to achieve a better and more equitable distribution of its benefits, with regard to the perception and knowledge of the different ethnic groups, cultures and human societies, in order to develop the science and technology that each believes is most appropriate to their own reality and without technology becoming an instrument for creating new forms of imposition, exploitation and dependency,**

~~Convinced that ethical reflection is an integral part of scientific and technological development and that bioethics plays today a predominant role in the social choices that need to be made,~~

~~Stressing the need~~ **That it is necessary** to reinforce international cooperation in the field of bioethics, taking into account **in particular the needs of the countries that are most vulnerable by virtue of their underdevelopment and poverty in particular the special needs of developing countries,**

~~Considering~~ that questions of bioethics raised by advances in science and technology, which have been addressed in part by the Universal Declaration on the Human Genome and Human

	<p>Rights and the International Declaration on Human Genetic Data, should be treated as a whole, drawing on the principles already affirmed in these two international instruments and taking account not only of the current scientific context but also of future developments,</p> <p>Proclaims the principles that follow and adopts the present Declaration.</p> <p>Therefore:</p> <p>In the light of the aforementioned considerations, DECLARES its full commitment to and endorsement of the principles and actions of bioethics, aimed at bringing about better standards conditions of living and housing on the planet, based on the following norms.</p>
<p>BRÉSIL/ BRAZIL</p>	<p>Suggests that the preamble refer to the following instruments: the United Nations Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948 (...), the United Nations Declaration on the Rights of Mentally Retarded Persons of 20 December 1971, the United Nations Declaration on the Rights of Disabled Persons of 9 December 1975, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978 (...), the ILO Convention (No. 169) concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989 (...), the United Nations Standard Rules on the Equalization of Opportunities for Persons with Disabilities of 20 December 1993.</p>
<p>CANADA</p>	<p>It is recommended as well that an additional statement be added as follows: “Recognizing that bioethical issues may impact on individuals, families, societies and humanity as a whole”. A statement to this effect serves to draw attention to a key consideration in addressing bioethical issues; this is well illustrated, for example, by the consideration of technologies that have the potential to alter the human germline.</p>
<p>ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA</p>	<p>Note: A further understanding is needed for the criteria to include international treaties and other agreements in the proposed declaration. In addition, Member States should not have to “recall” an agreement they have not accepted or adopted.</p> <p>“... Also recalling Noting the Universal Declaration of Human Rights of 10 December 1948, the two United Nations International Covenants...</p> <p>Also recalling Noting the Convention for the Protection of Human Rights and Dignity of the Human Being...</p> <p>Also recalling noting the international and regional codes of conduct and guidelines and other ethical texts in the field of science and technology,</p> <p><u>Considering</u> that, by virtue of its Constitution, it is incumbent upon UNESCO to promote “the democratic principles of the dignity, equality and mutual respect of men” and to reject any “doctrine of the inequality of men and races”, and that this constitutes a sacred solemn duty which all the nations must fulfil in a spirit of mutual assistance,</p> <p><u>Considering also</u> that it is the mission of UNESCO’s role to develop advance universal principles and norms based on shared values to guide scientific and technological development and social transformation, in order to meet emerging challenges in science taking into account the responsibility of the present towards future generations,</p> <p><u>Bearing in mind</u> UNESCO’s activities and programmes in the field of natural, social and human sciences, aiming at placing scientific and technological development in a context of ethical reflection, and at promoting the sustainable use and conservation of biological diversity and the improvement of the relationship between human beings and their environment,</p> <p><u>Aware</u> that human beings are an integral part of the biosphere and that they have responsibilities and duties towards other forms of life,-</p> <p><u>Recognizing</u> that scientific and technological developments have been of great benefit to humankind human beings in increasing <i>inter alia</i> life expectancy and improving quality of life and <u>emphasizing</u> that such developments should always promote the welfare of individuals and humankind as a whole in the recognition of the inherent dignity of the human person and the universal respect for human life, and observance of human rights and fundamental freedoms,</p> <p><u>Bearing in mind</u> that, without prejudice to the universal respect for, and observance of human rights and fundamental freedoms, cultural diversity, as a source of exchange, innovation and</p>

	creativity, is necessary for humankind and, in this sense, it is the common heritage of humanity; Convinced that ethical reflection is an integral part of scientific and technological development and that bioethics plays today a predominant role in the social choices that need to be made, Stressing the need to reinforce international cooperation in the field of bioethics, taking into account in particular while considering special needs of developing countries, ..."
MALI	7th paragraph: "Bearing in mind UNESCO's activities and programmes (...) and conservation of biological diversity and the relationship between human beings and their environment," 13th paragraph: " Considering that questions of bioethics raised by advances (...) drawing on taking into consideration the principles already affirmed in these two international instruments and ..."
MONACO	11th paragraph: " Convinced that ethical reflection is an integral part of is keeping pace with scientific and technological development and that bioethics ..."
SUISSE/ SWITZERLAND	12th paragraph: "Stressing the need to reinforce ..., taking into account in particular the special needs of developing countries, while respecting their autonomy ".

[USE OF TERMS] (LIMITED TO SCIENTIFIC TERMS)

BRÉSIL/ BRAZIL	More precise definitions need to be given to some basic concepts, including the term "bioethics" itself, in order to ensure that the Declaration is as consistent as possible.
ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	The terms should not only include scientific terms. Many terms used in this declaration need further clarification.
FINLANDE/ FINLAND	The key terms should be defined. Especially the term "bioethics" must be defined, otherwise the scope of the Declaration will extend too far.
INDE/ INDIA	Its inclusion in Article 1 will help in avoiding the repetitive use of the words "within the scope of this declaration".

GENERAL PROVISIONS

Article 1 – Scope

ALLEMAGNE/ GERMANY	"... (ii) apply to issues raised by scientific and technological developments and their applications in the field of biomedicine , as well as their availability and access." If the scope of the Declaration is too broadly defined, there is the danger that individual principles might not be applicable in all cases falling under the Declaration. This would detract from the Declaration's significance and relevance.
AUTRICHE/ AUSTRIA	A less ambitious definition of the scope of the declaration must be found as the present ambiguity impacts on other provision of the declaration such as Articles 8 seqq. If the decision is taken to extend the scope of the declaration beyond human beings, it will become necessary to differentiate the pertinence of the various principles included in the declaration according to the issues concerned, like human beings, biodiversity, biosphere, environment, to mention possible examples.
BELGIQUE/ BELGIUM	Article 1 (ii) should be clarified.
BOLIVIE/ BOLIVIA	"The principles set out upheld in this Declaration: i) apply to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere, and; ii) the biosphere and other forms of life that constitute biodiversity; iii) apply to issues situations resulting from scientific and technological developments and their applications, as well as situations concerning their availability and access; iv) situations that negatively affect the living conditions of a significant share of humankind."

CANADA	<ul style="list-style-type: none"> - It is recommended that “Scope” be made a primary heading, rather than being a sub-heading of “General Provisions”, in order to reflect the importance of this provision to the Declaration. - The reference to recognizing human responsibilities towards the biosphere is out of place and serves to cause confusion as to the scope of the document. This reference occurs more appropriately elsewhere, including in the Preamble and Article 7. - The reference to scientific and technological developments may be inappropriate, in the sense that there are significant bioethical issues that are only incidentally the product of any technical application. - Consequently, consideration should be given to amending the article on Scope along the following lines: “The principles of this Declaration apply to the resolution of bioethical issues that affect human beings including in the fields of research, public health, health care and biotechnology.” - It is also recommended that the phenomenon of technological convergence be recognized in the Scope section. For example: “The convergence of technologies such as informatics and nanotechnology with biotechnology is recognized, and the principles of this Declaration should be applied to these convergences to the greatest extent appropriate”.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	<p>“... (i) apply to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere, and (ii) apply to issues raised by scientific and technological developments in medicine and scientific research relating to human biology and human health and their applications, as well as their availability and access.”</p>
JORDANIE/ JORDAN	Scope should be consistent with recurrence in the Declaration of the statement “Any decision or practice within the scope of this Declaration...” . Besides, this recurring statement should be addressed under “Use of Terms”, which is perhaps not in line with stipulated restriction to scientific terms.
MEXIQUE/ MEXICO	With regard to the first part, we believe that "General Provisions" is an appropriate title, to be applied each time that general provisions, such as its scope of application, are set forth within the regulatory framework of the declaration, as opposed to definitions per se. It should be pointed out that the scope of application is worded in a very vague manner which could give rise to practical problems in the application of the principles of the future declaration.
MONACO	A single paragraph would be sufficient, namely: “... to human beings, while recognizing that human beings have responsibilities and duties towards other forms of life in the biosphere, depending on the issues raised”

Article 2 – Aims

BELGIQUE/ BELGIUM	<p>Article 2 should be redrafted as follows:</p> <ul style="list-style-type: none"> - “With a view to providing a universal framework of [fundamental] principles and [basic] procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, and forming the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned, the aims of this Declaration are: - to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance with human rights law; - to foster dialogue between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy makers and society as a whole; - to promote respect for biodiversity ...”
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<p>BOLIVIE/ BOLIVIA</p>	<p>“The aims of this Declaration are: ... - to ensure full respect for human beings for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance with human rights law; - to promote respect for biodiversity; - to safeguard the interests the living conditions of present and future generations, preserving biodiversity and the equilibrium of the biosphere and its ecosystems; - to recognize the great benefit derived from scientific and technological developments, whilst ensuring that such development occurs within the a framework of ethical principles that protect and promote life, respecting the dignity of human beings as well as their fundamental rights and freedoms, with equity and justice; respect human dignity and protect human rights and fundamental freedoms, and to prevent practices contrary to human dignity; - to promote the sharing and the greatest possible flow of knowledge concerning and benefits relating to scientific and technological developments as well as the sharing of benefits, in particular with developing countries; - to ensure that all human beings live under conditions in which their essence and dignity are respected and which adequately meet their needs for food, overall health, housing, education and individual and collective well-being, without prejudice to the natural environment and the ecological balance; - to permanently promote justice, freedom, peace and solidarity for all human beings as a fundamental principle to be upheld by all governments and a jointly-shared planetary aim; - to develop a level of collective awareness that motivates, prepares and mobilizes society in defence of life, confronting any circumstance that suppresses, affects or damages it; - to ensure that drugs are available to all individuals who need them, without the economic globalization of free-trade treaties and the issue of patents inevitably becoming an obstacle to attaining that goal; - to foster open dialogue concerning unresolved problems and issues in the field of bioethics.”</p>
<p>CANADA</p>	<p>New formulation: “The aims of this Declaration are: ▪ to provide a universal framework of principles and procedures to guide States in the resolution of bioethical issues associated with proposed and existing legislation, policies, programmes and initiatives; ▪ to assist in the development, interpretation and application of existing and future bioethics instruments, including the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data; ▪ to encourage organizations, professionals and general society to address bioethical issues in accordance with this universal framework of principles and procedures; ▪ to foster dialogue with respect to the resolution of bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians, other professionals and policy makers, and general society; and ▪ to promote the sharing of knowledge concerning scientific and technological developments, as well as the sharing of benefits, in particular with developing countries.”</p>
<p>ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA</p>	<p>“... • to provide a universal framework of fundamental principles and basic procedures designed to guide States in the formulation of <i>national</i> their legislation and their policies in the field of bioethics, <i>namely, ethical principles and practices relating to human biology and human health</i>, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned; • to ensure <i>promote</i> the respect for <i>human life</i>, human dignity and the protection of human rights and fundamental freedoms in [the sphere of] research, development, and application of medical and other life sciences, and other fields affecting human biology and human health, bioethical decision-making, in accordance with human</p>

	<p>rights domestic law and accepted international principles consistent with protection of human dignity and autonomy law;</p> <ul style="list-style-type: none"> • to promote respect for biodiversity; • to recognize the great benefit derived from scientific and technological developments, in medicine and scientific research, to promote such developments whilst ensuring promoting that such development they occurs within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms, and to prevent practices contrary to human dignity; • to foster dialogue between among scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual and professional groups concerned, policy makers and society as a whole; • to promote the sharing and the greatest possible exchange flow of knowledge concerning scientific and technological developments as well as the sharing of benefits, in particular with developing countries; • to safeguard the interests of present and future generations.”
JORDANIE/ JORDAN	<p>“... - to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in the sphere of bioethical decision making, in accordance with human rights law;”</p>
KAZAKHSTAN/ KAZAKHSTAN	<p>“... - to promote respect for biodiversity and ethical norms of animal use,”</p>
MEXIQUE/ MEXICO	<p>“... - to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in the sphere of bioethical decision making, in accordance with human rights law;”</p>
MONACO	<p>“... - to provide a universal framework of fundamental principles and basic procedures designed to help States in the formulation of their legislation and... ; ... - to recognize the great benefit derived from scientific and technological developments, whilst ensuring that they occur within the framework of ethical principles which, respecting human dignity and protecting human rights and fundamental freedoms, prevent practices contrary to human dignity ; »</p>
SUISSE/ SWITZERLAND	<p>“... - to promote respect for all living beings and for biodiversity; »</p>
SAINT SIÈGE/ HOLY SEE	<p>“... - to ensure respect for human life, health, human dignity and the protection of human rights and ... ; ... - to promote the education of society and in particular young people with regard to the values and principles from which the positions of bioethics are derived, the sharing and the greatest possible flow of knowledge ...;”</p>

GENERAL [FUNDAMENTAL] PRINCIPLES

AUTRICHE/ AUSTRIA	The proposed division of principles should be dropped.
BELGIQUE/ BELGIUM	<p>A single heading (Principles), containing all three categories of principle (fundamental, derived and procedural), is preferable to the current arrangement. The articles should be organized under that heading and amended as follows: Article 3 – Human Dignity and Human Rights Article 4 – Primacy of the Human Person Article 5 – Non-Discrimination and Non-Stigmatization Article 6 – Autonomy and Responsibility Article 7 – [Informed] Consent Article 8 – Privacy and Confidentiality Article 9 – Responsibility towards the Biosphere</p>

	Article 10 – Beneficence and Non-Maleficence Article 11 – Respect for Cultural Diversity and Pluralism Article 12 – Sharing of Benefits
CANADA	Consideration should be given to doing away with the distinction between fundamental and Derived principles, and an effort made to express these principles in a fashion that makes clearer their application between the State and the individual.
FINLANDE/ FINLAND	It is difficult not to get a hierarchical impression of principles. If this is to be avoided, a better heading would be “General Principles”, but if the intention is to underline the fundamental nature of the principles, then the heading “Fundamental Principles” would be better.
MEXIQUE/ MEXICO	The second part should be entitled “Fundamental Principles”, since its content corresponds precisely to fundamental principles and not so much to general principles. The adjective “general” is more appropriate for provisions affecting the whole in a general way, without themselves being ‘fundamental values’.
PORTUGAL	The option “Fundamental Principles” is to be preferred to “General Principles”.
ROUMANIE/ ROMANIA	Our preference is for “General Principles”, which can be interpreted and understood more easily than “Fundamental Principles”, which might suggest that somebody could set themselves up as a decision-maker on what is fundamental.
SAINT SIÈGE/ HOLY SEE	Instead of General [Fundamental] Principles, we could refer to Fundamental [General] Principles.

Article 3 - Human Dignity, Human Rights and Justice

AUTRICHE/ AUSTRIA	“Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms and for the universal principle of justice. ”
BELGIQUE/ BELGIUM	“Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms and for the universal principle of justice. ”
CANADA	“Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms and for the universal principle of justice. ” Consideration should also be given to adding a sentence to address the reality of new technologies: “The resolution of bioethical issues associated with proposed and existing legislation, policies, programmes and initiatives shall respect international human rights law and principles, and in particular shall promote and protect the dignity of the individual. New technologies require the application and implementation of international human rights law and principles to new situations.”
ÉTATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Any decision or practice within the scope of this Declaration shall should be made or carried out with full respect for the inherent dignity of the human person and for the universal principle of justice, consistent with ; human rights and fundamental freedoms and for the universal principle of justice. ”
FRANCE	Article 3 would probably gain in force if it individualized the principle of respect for the dignity of the human person, which should be treated separately as a central element of the Declaration. The universal principle of justice could be the subject of a separate article.
MONACO	[Applicable only to the French.]
SUÈDE/ SWEDEN	The text refers to principles that not are explained. How should <i>human dignity</i> be interpreted? What is included in the concept <i>human rights</i> ? Which is the <i>universal principle of justice</i> ? Also, it is not obvious why these three principles are grouped in the same article.
SAINT SIÈGE/ HOLY SEE	“Any decision or practice ... with full respect for the life and inherent dignity ...”

Article 4 - Beneficence and Non-Maleficence

BELGIQUE/ BELGIUM	Belgium would like an explanation as to the meaning and scope of these terms since they are not French. Belgium could agree to the alternative wording “ Benefit and Reduction/Limitation of Harm ”.
BOLIVIE/ BOLIVIA	“Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice to the persons or human groups involved. ”
CANADA	Consideration should be given to dividing beneficence and non-maleficence into separate articles in the present declaration.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Any decision or practice within the scope of this Declaration shall should seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice {to the persons concerned}. ”
FRANCE	Article 4 as currently worded (Beneficence and Non-Maleficence) is hard to understand, and in any event too wide-ranging. The usefulness of these concepts in this precise instance warrants further explanation.
JORDANIE/ JORDAN	“Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice {to the persons concerned}. ”
MEXIQUE/ MEXICO	“Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice {to the persons concerned}. ”
MONACO	“Any decision or practice within the scope of this Declaration should aim to produce the best effects and seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice {to the persons concerned}. ”
PAYS-BAS/ THE NETHERLANDS	“Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice {to the persons concerned}. ” Adding the wording “to the person concerned” could have the result of limiting the scope as set out in Article 1 and of narrowing the aims as set out in Article 2. It would be preferred to leave out this text between brackets.

Article 5 - Respect for Cultural Diversity and Pluralism

AUTRICHE/ AUSTRIA	Austria considers it impossible to take the aspects referred to in this article into account in any decision in practice. More importantly however Austria could not agree with the second sentence without clear reference to international human rights law as a set of principles which must not be infringed.
BELGIQUE/ BELGIUM	“Any decision or practice within the scope of this Declaration shall take into account the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions and religious and philosophical beliefs religious beliefs and like considerations. However, cultural diversity [such considerations] shall [may] not be invoked to infringe upon the universal principles set out in this Declaration, nor to limit their scope.”
BOLIVIE/ BOLIVIA	New wording: “Any decision or practice within the scope of this Declaration shall take into account the variety of the axiological, cultural, ethnic, doctrinal, historic, social and philosophical background of persons and societies, which may not however be invoked to disregard or violate the universal principles set out in this Declaration, or affect their application. ”
CANADA	“Any decision or practice within the scope of this Declaration shall take into account the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious beliefs and like considerations that make up our societies. ... ”
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Article 5 - Respect for Cultural Diversity Differences and Pluralism Any decision or practice within the scope of this Declaration shall should take into account consideration the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious beliefs and like considerations. However, cultural diversity ”

	{such considerations] shall should not be invoked to infringe upon the universal principles set out in this Declaration, nor to limit their scope.”
FRANCE	Article 5 paves the way to a potentially harmful use of the essential concept of cultural diversity, which might call into question universally accepted principles of human rights. The wording of this article could usefully distinguish between the intangible principles set out in the Declaration (and continued in other texts on human rights) and the necessary taking into account of cultural diversity in their implementation.
LETTONIE/ LATVIA	The article needs revision due to uncertainty and pluralism in its interpretation. From one side, an article declares that any decision or practice shall take into account the cultural backgrounds, schools of thought, etc. From the other side, all these considerations shall not be invoked to infringe upon the universal principles of Declaration.
MEXIQUE/ MEXICO	There are serious difficulties with regard to Article 5. The term “cultural diversity” encompasses those cultural expressions that include and generate the values that the Declaration aims to protect, so that contrasting them seems, up to a certain point, paradoxical. If it is understood that the objective of Article 5 is to prevent a certain – not universal – value being used to justify acting against human rights and human dignity in the context of decisions on bioethics, it is in the end extremely complicated to disentangle universal human values from various cultural expressions, since they include values that are in fact universal.
MONACO	“Any decision or practice within the scope of this Declaration shall take into account the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, and religious beliefs and like considerations . However, cultural diversity [such considerations] shall not be invoked to infringe upon the universal principles set out in this Declaration, nor or to limit their scope.”
PAYS-BAS/ THE NETHERLANDS	The text between brackets (such considerations) may have the advantage of assuring that all the considerations mentioned in the text are covered.
SUÈDE/ SWEDEN	There seems to be a conflict between taking a number of aspects into account, whilst at the same time those aspects are not supposed to invoke or infringe upon the universal principles set out in the declaration. What is the specific meaning of the term <i>take into account</i> in this article?
TURQUIE/ TURKEY	“Any decision or practice within the scope of this Declaration shall take into account the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious beliefs and like considerations. However, cultural diversity [such considerations] shall not be invoked to infringe upon the universal, so far as they are not contradictory to human rights and to the principles set out in this Declaration, nor to limit their scope.” The wish to avoid the discrimination of human beings, made on the ground of their different cultural identities, does not imply respect to all <u>cultural norms</u> , many of which are not in accordance with human rights.

Article 6 - Solidarity, Equity and Cooperation

AUTRICHE/ AUSTRIA	The concepts enumerated in this article would have to be defined before being introduced as principles for the draft declaration. Furthermore the principles of “Non-Discrimination and Non-Stigmatization” are specifically mentioned in Article 9 – albeit without being consistent with the norms of international human rights law.
CANADA	This article is a good example of the difficulties created by the proposed distinction between fundamental and Derived principles, for the ideas raised in this article are subsequently raised, with more clarity, in Articles 9 and 13.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Any decision or practice within the scope of this Declaration shall should respect the solidarity of humanity, ensure promote equity and encourage international cooperation [, in order <i>inter alia</i> to avoid discrimination and stigmatization of an individual, a family or a group]. ” The bracketed language is later addressed in Article 9. Also, the concepts of “solidarity” and “equity” need clarification.

FINLANDE/ FINLAND	<p>“Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure equity and encourage international cooperation [in order <i>inter alia</i> to avoid discrimination and stigmatization of an individual, a family or a group].”</p> <p>The text in square brackets is repeated under the next heading in Article 9.</p>
FRANCE	<p>“Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure equity and encourage international cooperation [in order <i>inter alia</i> to avoid discrimination and stigmatization of an individual, a family or a group].”</p>
JORDANIE/ JORDAN	<p>“Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure equity and encourage international cooperation[in order <i>inter alia</i> to avoid discrimination and stigmatization of an individual, a family or a group].”</p>
MONACO	<p>“Any decision or practice within the scope of this Declaration shall respect the ensure solidarity of among humankind, ensure and equity and encourage international cooperation [in order <i>inter alia</i> to avoid any discrimination and stigmatization of an among individuals, a family families or a groups].”</p>
PAYS-BAS/ THE NETHERLANDS	<p>The solidarity, equity and cooperation mentioned in this article are welcomed. The proposed additional wording between brackets (in order to....group) is considered to be superfluous, and may even occasionally have a harmful influence on the protection of inherent human dignity as embodied in Article 3.</p>
SUÈDE/ SWEDEN	<p>“Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure promote equity and...”.</p>
SUISSE/ SWITZERLAND	<p>Articles 5 and 6 are of great importance and must not under any circumstances be deleted.</p>

Article 7 - Responsibility towards the Biosphere

AUTRICHE/ AUSTRIA	<p>What would be the reasons for and the benefits of restricting this responsibility to the biosphere “within which human beings exist”? Such a provision can only harm the intentions of the declaration.</p>
CANADA	<p>It is recommended that the phrase “within which human beings exist” be dropped. At its best, the phrase is unnecessary. At its worst, the sentence could be read to mean that we need only be concerned about those particular environments in which humans actually live – for example, this principle would not apply to protection of ocean life.</p>
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	<p>The concept of responsibility towards other life forms is important to acknowledge in the preamble, but should not be a major principle in a bioethics declaration targeting human beings.</p>
KAZAKHSTAN/ KAZAKHSTAN	<p>“Any decision or practice within the scope of this Declaration shall have due regard for their impact on all forms of life and their interconnection and the special responsibility of human beings for the protection of biodiversity including biosafety from possible negative action from gene modified organisms and the biosphere within which human beings exist.”</p>
MONACO	<p>“Any decision or practice within the scope of this Declaration shall have due regard for their impact on all forms of life and their interconnection and the special responsibility of human beings for in the protection of biodiversity and the biosphere within which human beings exist.”</p>
SUÈDE/ SWEDEN	<p>The concept “<i>due regard</i>” is problematic. What is the definition of the concept, and who (or which authority) is to decide when a decision or a practice have <i>due regard</i>?</p>
SUISSE/ SWITZERLAND	<p>“Any decision or practice within the scope of this Declaration shall have due regard for their impact on all forms of life and their interconnection, for the respect and the special responsibility of human beings with regard to living beings, for the protection of biodiversity and the biosphere within which human beings exist.”</p> <p>The title should be amended to read as follows: “Respect and Responsibility towards the Biosphere”.</p>

DERIVED PRINCIPLES

Article 8 - Primacy of the Human Person

AUTRICHE/ AUSTRIA	The meaning of this provision is not clear as it merely notes that the interest of the individual shall prevail over the interest of society (interrelation with the optimization/maximization rule enshrined in Article 4 of the draft).
CANADA	The meaning of the word “sole” in Article 8 is unclear. This provision appears to have its origins in the Council of Europe Convention on Human Rights and Biomedicine. Clarification of the meaning of this provision would be useful.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Any decision or practice within the scope of this Declaration shall should be founded on the recognition of the primacy of the human person, and should be consistent with the universal principles of human dignity, human rights and fundamental freedoms which shall prevail over the [sole] interest of science or society. ”
FRANCE	Can the primacy of the human person really be considered to be a derived principle ?
JORDANIE/ JORDAN	Inclusion of “sole” is preferable.
MEXIQUE/ MEXICO	Inclusion of “sole” is preferable.
MONACO	Inclusion of “sole” is preferable.
PAYS-BAS/ THE NETHERLANDS	Inclusion of “sole” is preferable.
PORTUGAL	Article 8 should follow on from Article 3, as it cannot be considered to be a derived principle as it is an absolutely fundamental principle.

Article 9 - Non-Discrimination and non-Stigmatization

BOLIVIE/ BOLIVIA	“In any decision or practice within the scope of this Declaration, no one human being shall be subjected to discrimination based on any grounds...”
CANADA	<ul style="list-style-type: none"> - In Article 9, the enumerated grounds of discrimination do not adequately reflect international human rights law. It is recommended that they be replaced by a reference to “any ground prohibited by international human rights law”, so as to include all grounds of prohibited discrimination and allow for the evolution of human rights law. - Given the subject matter of the Declaration, consideration could be given to supplementing this general reference with a specific, inclusive reference to “medical condition or genetic characteristics.” - Consideration should be given to adding the word “exclude” after “stigmatize”, to make the provision consistent with the ECOSOC resolution on <i>Genetic Information and Privacy</i>. - The inclusion of a reference to the need for gender-based analysis should be considered, because some bioethics issues impact differently on women than on men.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	<p>“In any decision or practice within the scope of this Declaration, no one shall should be subjected to discrimination based on any grounds, including physical, mental or social conditions, diseases or genetic makeup characteristics or disabilities, nor shall should such conditions or characteristics be used [invoked] to stigmatize an individual, a family or a group.”</p> <p>Justified discrimination will not be allowed under this provision as written. Examples of justified discrimination include studies to determine effective treatments in a certain population (e.g. Asians).</p>
JORDANIE/ JORDAN	“Invoked” is preferable.
MONACO	“In any decision or practice within the scope of this Declaration, no one shall be subjected to any discrimination based on any grounds , including ...”.

SUÈDE/ SWEDEN	The term “ <i>discrimination</i> ” should be defined in such a way that the concept is not ethically objectionable.
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Article 10 - Autonomy and Responsibility

BOLIVIE/ BOLIVIA	“Any decision or practice within the scope of this Declaration shall respect the autonomy of a person as an expression of his/her liberty to make decisions, and shall be without prejudice to the autonomy of others.”
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	Replace “shall” by “should”.
SUISSE/ SWITZERLAND	Title: “Autonomy and Responsibility Respect for the Autonomy of Others ”.

Article 11 - [Informed] Consent

BELGIQUE/ BELGIUM	b) When, in accordance with domestic law, consistent with international human rights law, a person does not have the capability to give is incapable of giving consent, such consent [authorization] should be obtained from his / her legal representative, having regard to the best interest of the person concerned.”
BOLIVIE/ BOLIVIA	“a) The prior, free, informed and express consent of the persons concerned shall be obtained in all medical, or scientific or other kind of research to be undertaken with or in relation to them, and in the application of any treatment or diagnostic method diagnosis . Such consent may be withdrawn at any time. b) When, in accordance with domestic law consistent with international human rights law, a person is incapable of giving consent, such consent [authorization] should be obtained from his / her legal representative, having regard to the higher best interest of the person concerned.”
BRÉSIL/ BRAZIL	“b) When, in accordance with domestic law consistent with international human rights law, a person is incapable of giving consent, such consent [authorization] should be obtained from his/her legal representative, having regard to the best interest of the person concerned. In such cases, all medical or scientific research, treatment or diagnosis may only be carried out for his/her direct health benefit. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual’s human rights. ” <i>(In accordance with Article 5 of the Universal Declaration on the Human Genome and Human Rights)</i>
CANADA	- Article 11 would appear to extend the requirement for prior, express consent to the secondary use of non-identifiable or aggregate data. Is this intended? The treatment of secondary use of such data is a matter of on-going debate both within countries and internationally. The same issue arises with Article 12. - It is recommended that paragraph (b) of Article 11 be re-drafted to conform to the language of Article 8(b) of the <i>International Declaration on Human Genetic Data</i> for the sake of consistency and to avoid changes in meaning between the two provisions.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“a) The prior, free, informed and express consent of the persons concerned shall should be obtained in all medical or scientific research, treatment or diagnosis, except as provided for in domestic law, consistent with the international principles consistent with protecting human life, dignity and autonomy . Such consent may be withdrawn at any time. b) When, in accordance with domestic laws and policies , consistent with accepted international principles of human dignity, human rights and fundamental freedoms human rights law , a person is incapable of giving consent, such consent [authorization]

	should be obtained from his / her legal representative, having regard to for the best interest of the person concerned.”
FINLANDE/ FINLAND	In Article 11 the consent is consistently required to be “express”. In medical care, it may also be “implicit” and in emergency situations the patient is given the treatment considered to be the best in the situation without his/her consent or authorization by some other person. As far as medical treatment is concerned, it is not always possible in an emergency to ask for the consent of the person concerned.
JORDANIE/ JORDAN	- Title: “Informed consent”. - Delete “authorization”.
MEXIQUE/ MEXICO	The title of Article 11 should be “ <i>Informed Consent</i> ”, as it reflects better the idea contained in the text. In order to ensure theoretical consistency, the word “ <i>consent</i> ” should be preferred to the word “ <i>authorization</i> ” in subparagraph (b). Furthermore, in line with rigorous legal terminology, individuals express their free consent, whilst the authorities <i>authorize</i> .
PAYS-BAS/ THE NETHERLANDS	- Title: “Informed consent”. - With respect to subparagraph (b), the Netherlands wish to express the view that the protection of persons who are incapable of giving consent is of utmost importance. The inclusion of an extra reference to human rights is therefore certainly welcomed. - Against this background, the Netherlands also express the view that the wording “such consent should be obtained from his/her legal representative” is rather narrow. As a suggestion for an alternative wording the following formulation could be helpful: “ such consent (authorization) should be obtained of his or her representative or an authority or a person or body provided for by law ”. This would be in conformity with the text of the Convention on Human Rights and Biomedicine of the Council of Europe.
SUÈDE/ SWEDEN	The informed consent needs to be expressed in a more balanced way, and the text needs to be adjusted to agree with international declarations for research ethics.
SUISSE/ SWITZERLAND	Article 11, referring to research involving human beings, is too restrictive in relation to consent given by others. In addition to the legal representative, it is possible to have recourse to close relatives or refer to a living will in order to obtain consent. Furthermore, greater distinction should be made between a situation where a research project is aimed at direct benefit for the person concerned, and one where a benefit is only of use to society or a specific group.

Article 12 – Privacy and Confidentiality

ÉTATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Any decision or practice within the scope of this Declaration shall shall should be made or carried out with full respect for the privacy of the persons concerned and the confidentiality of their personal information. Such information cannot should not be used or disclosed for purposes other than those for which it was collected, except with the consent of the person concerned or in cases restrictively provided for by domestic law consistent with accepted international principles of respect for privacy and confidentiality human rights law. ”
JORDANIE/ JORDAN	“..... full respect for the privacy of the persons concerned...”
MEXIQUE/ MEXICO	“..... full respect for the privacy of the persons concerned...”
PORTUGAL	“Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for the privacy of the persons concerned ...” There are circumstances in which certain values such as respect for the life of others may restrict the duty of confidentiality, as referred to subsequently in the Article.
SÉNÉGAL/ SENEGAL	It would be useful to provide for appropriate measures in the event of failure to respect the confidentiality of genetic information concerning the individual (compensation, reparation of the prejudice suffered, and so on).

SUISSE/ SWITZERLAND	Article 12 should be completed by the following principle, namely that the gathering of information should not only serve a specific purpose but must also be authorized by the person concerned.
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Article 13 - Sharing of Benefits

BOLIVIE/ BOLIVIA	“In accordance with international and domestic law, benefits...: ... (vi) Respect for free choice and the interests or needs of beneficiaries; (vii) Benefit in direct relation to the needs of the beneficiary; ...”
CANADA	It is recommended that the opening phrase of Article 13 should be made consistent with the corresponding phrase in Article 19 of the <i>International Declaration on Human Genetic Data</i> . Canada understands that the reference to international law means that the principle of benefit sharing is to be applied in a manner consistent with international law governing the protection of intellectual property.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	In accordance with international and domestic law, benefits resulting from biomedical and other scientific research relating to human biology and human health , and their applications should be shared with the society as a whole and the international community . In giving effect to this principle, benefits may take any form consistent with the principles set out in this Declaration . Such benefits might include the following: of the following forms: (i) special assistance to the persons and groups that have taken part in the research; (ii) promoting access to medical care; (iii) provision of new diagnostics, facilities for new treatments or drugs stemming from the research; (iv) promoting support for health services; (v) access to scientific and technological knowledge, in particular for developing countries; (vi) capacity-building facilities for research purposes; (vii) any other form consistent with the principles set out in this Declaration.
FINLANDE/ FINLAND	Article 13 raises questions of patents and immaterial rights. It is to be noted that the article differs from the others in that it deals with the details of a given topic. Although the content of the article is to be endorsed as such, it would be worthwhile to reconsider deleting it.
FRANCE	Subparagraphs (vi) and (vii) of Article 13 should probably be reworded for greater precision.
JORDANIE/ JORDAN	“In accordance with international and domestic law, benefits resulting from scientific research and their applications, including financial support , should be shared with the society...: ... (v) access to and transfer of scientific and technological knowledge, in particular for developing countries; ...”
MALI	“(vi) capacity-building facilities and infrastructure for research purposes;”
MONACO	“(ii) universal access to medical care;”
PAYS-BAS/ THE NETHERLANDS	Should we limit this principle to publicly funded research or can we indeed rightfully adopt a wider ethical norm?
SUÈDE/ SWEDEN	Nothing is declared regarding the percentage of the benefit that should be shared, nor which agencies that should receive part of the profit. It is not likely that e.g. pharmaceutical companies will agree on such a benefit sharing. A consequence is that it probably will be difficult to give this article a precise meaning.
TURQUIE/ TURKEY	“In accordance with international and domestic law, benefits resulting from scientific research and their applications should be shared with the society the international community as a whole and the international community . In giving effect to this principle, benefits may take any of the following forms States shall enter into bilateral or multilateral agreements defining the modes of any scientific research within the scope of this Declaration, to provide: ...”

PROCEDURAL PRINCIPLES

ALLEMAGNE/ GERMANY	It still seems somewhat unclear what exactly the “Procedural Principles” mean. They do not seem to be well coordinated and do not apply in all cases. For example, the “independence” required by Article 14 (i) must not be understood as excluding “dependent” industrial research or research funded by third parties. It must also be stated clearly that evaluation measures such as the assessment by ethics committees envisaged in Article 20 do not imply any limitation of independence. Article 14 (iv) seems to relate to aspects of Article 15; Article 15 (iv) should not be understood as meaning that every individual measure is to be scrutinized by the persons concerned and by civil society.
FRANCE	Some of the procedural principles seem to be difficult to define or understand in the context of this Declaration: what is meant exactly by “independence and intellectual honesty”? In order to prevent such concepts being deliberately misinterpreted twisted by certain regimes, they should be defined more precisely. The same remark could be made about the “fair procedures” referred to in Article 18.
SUISSE/ SWITZERLAND	We would like to stress that Articles 14 to 18 on procedural principles are excellent, in our opinion, and should not be modified at all.

Article 14 - Honesty and Integrity

BELGIQUE/ BELGIUM	“(iv) pay due regard to the need to inform the persons affected and/or to share knowledge about such decisions and practices with them the persons affected , the scientific community, relevant bodies and civil society.”
MALI	“(iv) pay due regard to the need to share knowledge about such decisions and practices with the persons and bodies affected, the scientific community relevant bodies and civil society.”
MONACO	“(ii) respect the need for demonstrate integrity in scientific and other research;”
SAINT SIÈGE/ HOLY SEE	“(iii) avoid conflict of interest and duty, which should not prevent the application in treatment of an action with a dual effect (one good and the other bad) ”.

Article 15 - Transparency and Openness

BELGIQUE/ BELGIUM	Belgium would like explanations as to subparagraph (ii).
CANADA	The reference to “persons concerned” in paragraph (ii) is unclear. Just who is meant by this phrase in this article? With respect to paragraph (v), is the term “susceptible” the best one? The intent of this provision is unclear.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“Any decision or practice within the scope of this Declaration shall should, where applicable: (i) be made transparently and openly while maintaining the privacy and confidentiality of the persons concerned; (ii) be determined with particular regard to the circumstances known to the persons concerned; (iii) be subject to respect for privacy and confidentiality [as stated in Article]; (iv) be available for appropriate scrutiny examination by the persons concerned and by civil society; and (v) be susceptible to informed and pluralistic public debate, including in the media.

Article 16 - Scientific and Rational Methods

BELGIQUE/ BELGIUM	Belgium would like to know what is meant by “decision-maker” and an explanation of the phrase “in a principled manner”.
CANADA	The meaning of paragraph (v) is unclear.

ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	“Any decision or practice within the scope of this Declaration shall should : (i) be made on the best available scientific information ; including any relevant scientific and medical evidence on the subject reasonably available to the decision-maker; (ii) pay due regard to any different information (iii)(ii) be considered rigorously and in a principled manner ; in accordance with accepted principles of rigorous scientific analysis ; ...”.
JORDANIE/ JORDAN	The words/phrases “reasonably”, “when appropriate”, “allowing for the possibility” make the statements of the article subject to value judgment. Rewording is needed.
KAZAKHSTAN/ KAZAKHSTAN	New: “(vi) be carried out in according with ethical norms in experiment in animals ”.
MALI	“(iii) be considered rigorously and in a principled manner consistent with the principles set out in this Declaration. ”
MONACO	“(iii) be considered rigorously and in a principled manner consistent with the principles set out in this Declaration. ”
PAYS-BAS/ THE NETHERLANDS	Meaning of indent (iii) asks clarification. The French text seems to be clearer (“examinee” as compared to “considered”). Indent (v) also asks for clarification, since it seems to be rather abstract.

Article 17 - Community and Expert Consultation

BOLIVIE/ BOLIVIA	New: “(v) government bodies ”.
ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	Replace “shall” by “should”.
MONACO	“Any decision or practice within the scope of this Declaration, including those depending upon specialized scientific or other knowledge, shall...”.
PORTUGAL	“(iii) appropriate bodies, including bioethics councils, committees and commissions ”.

Article 18 - Fair Decision-Making Process

BOLIVIE/ BOLIVIA	“Any decision or practice within the scope of this Declaration, where differences arise, shall be resolved following full and free discussion and in accordance with fair legal procedures.”
ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	Replace “shall” by “should”. Clarification is needed for this article with respect to the parties to resolve the differences, and what is meant by “fair procedures”.
MONACO	“Any decision or practice within the scope of this Declaration, where differences arise, shall only be resolved following full and free discussion and in accordance with fair procedures.”
PAYS-BAS/ THE NETHERLANDS	The wording “resolved” is not clear. The French version uses “mise en oeuvre” in this article as well as in Article 16 indent (i), whereas the English equivalent there is “made”. There would be an interest in aligning the texts further.

PROCEDURES

Article 19 - Risk Assessment

BOLIVIE/ BOLIVIA	“When there is scientific evidence of threats of serious or irreversible damage to individual and public health and human welfare or the environment [biosphere], provisional adequate...”
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<p>DANEMARK/ DENMARK</p>	<p>“When there is scientific evidence of threats of serious or irreversible damage to public health and human welfare or the environment (biosphere), or when there is a well-based suspicion of this, provisional adequate and proportionate measures shall be taken in a timely manner. Such measures shall be based on the best scientific knowledge available and based on procedures that are specially designed for evaluating the ethical issues connected to the question at hand. These measures should be carried out in accordance with the principles set out in this Declaration and with respect to human rights and fundamental freedoms.”</p> <p>It is acceptable that the declaration does not refer to the precautionary principle as such. However, the article dealing with risk assessment should include that the principle is not only a reason for “taking measures” when there is “scientific evidence of threats etc.” as stated in Article 19 but also when there is a well-based suspicion thereof.</p>
<p>ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA</p>	<p>What would the criteria to determine “threats of serious or irreversible damage to public health and human welfare or the environment”? Who would determine such threats? Who would take “provisional adequate and proportionate measures”? How would one define “adequate” “proportionate” and “event timely” given a serious threat? We suggest deletion of this article.</p>
<p>FINLANDE/ FINLAND</p>	<p>The Declaration appears to extend too far in Article 19 “Risk Assessment”, which concerns, for instance, threats to the environment.</p>
<p>JORDANIE/ JORDAN</p>	<p>The term “environment” is preferable.</p>
<p>MEXIQUE/ MEXICO</p>	<p>Articles 19, 21 and 22 are not strictly speaking procedures, but procedural principles and should therefore form part of the section entitled “Procedural Principles”.</p>
<p>PAYS-BAS/ THE NETHERLANDS</p>	<p>Article 10 paragraph 6 of the Protocol to the Convention on Biological Diversity is formulated in a more stringent way than Article 19 of the present Declaration. Is this difference intended?</p>
<p>SUISSE/ SWITZERLAND</p>	<p>Article 19 is about risk assessment and describes the principle of precaution. In particular, the scope of the reference to “scientific evidence” is highly controversial in the debate on this principle. Clarification would be desirable, as, in particular for new technologies, scientific evidence is lacking and it is not possible to have recourse to this criterion alone as an incentive to take provisional precautionary measures. In such cases, scientific uncertainty plays a dominant role.</p>
<p>TURQUIE/ TURKEY</p>	<p>New formulation: “Risk Management and the Precautionary Approach Any decision or practice within the scope of this Declaration shall ensure a high level of protection for the individual and public health. In order to pursue this objective, the States shall take measures based on risk assessment, taking into account all relevant risk factors, including technological aspects, the best available scientific evidence... Where a full risk assessment is not possible, measures should be based on the precautionary principle.”</p>

Article 20 - Ethics Committees

<p>ALLEMAGNE/ GERMANY</p>	<p>Ethics committees should not be called upon to look into general “technological developments”; their involvement should be confined to research projects that are conducted on human beings or identifiable human biological material.</p>
<p>AUTRICHE/ AUSTRIA</p>	<p>The question is whether bioethics committees can reasonably be expected to shoulder the tasks proposed (“to assess the ethical, legal and social issues ...”).</p>
<p>ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA</p>	<p>“Independent and multidisciplinary and pluralist ethics committees should be established, promoted, and supported and evaluated over time at the appropriate level in order:</p> <ul style="list-style-type: none"> (i) to assess the ethical, legal and social issues related to scientific research projects and technological developments in health; and (ii) to devise guidelines and recommendations on issues within the scope of this Declaration, in accordance with the principles set out therein.” <p>How is this committee to be formed? It will require needs, charter, role, and functions to be identified. The composition of such a committee will require much further discussion. For example, would this be an international ethics committee reviewing policies? What</p>

	transparency requirements will apply to its work? What process requirements will apply to the development of the guidelines? How would this functionally differ from the existing committees?
JAPON/ JAPAN	It is necessary to explicate clearly within this provision the concrete requirements each country has to fulfil. For example, this article states that the ethics committees should be independent. However, it is not clear whether it means juridical independence from the government or not, and whether the committees whose reports or recommendations must be concretized by the authority are independent or not. If the scope of the clauses is not clear enough, it is not possible to decide whether the words used in the clause are appropriate or not.
MONACO	“(ii) to devise guidelines and recommendations on issues...”
SUISSE/ SWITZERLAND	Ethics committees should be advisory committees.

Article 21 - Ensuring Public Debate

ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“States should ensure that citizens have endeavour to provide an opportunity for informed, pluralistic public debate, ensuring encouraging the participation of all the stakeholders concerned and the relevant bioethics committee, and the expression of various socio-cultural, religious and philosophical opinions.”
SUISSE/ SWITZERLAND	The promotion of full participation in public debate, as provided for under Article 21, is particularly salutary.

Article 22- Transnational Practices

BOLIVIE/ BOLIVIA	“International research should be subjected to ethical review in the country providing financial support for the activity as well as in the country where the research is to be carried out. This review should be based on the principles set out in this Declaration and on the established universal body of norms in force on research. ”
BRÉSIL/ BRAZIL	An article could be added stipulating that a country is prohibited from providing, or enabling the provision of any financial support enabling research activities prohibited in its own territory to be conducted in another country.
CANADA	Consideration should be given to supplementing the proposed provision with a more positive obligation on the part of a State that is supporting work being carried out in another State. A possible provision might read as follows: “ A State that provides financial or other support to an activity with bioethical implications, which will be undertaken in whole or in part in another State, should take all reasonable measures to ensure that the initiative complies with the principles of this Declaration. Non-State sponsors of and professionals associated with a transnational initiative should also take all reasonable measures to achieve the same end. ” Consideration should be given to calling for the development of bioethical impact analysis, as an element in addressing bioethical issues associated with proposed and existing legislation, policies, programmes and initiatives.
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“ International research on human biology and human health should be subjected to ethical review. in the country providing financial support for the activity as well as in the country where the research is to be carried out. This review should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.”
FRANCE	France endorses the wording of Article 22.
JORDANIE/ JORDAN	Jordan prefers to include this article into the text of the Declaration.
LETTONIE/ LATVIA	Latvia prefers to include this article into the text of the Declaration.
MEXIQUE/ MEXICO	The proposal contained in Article 22 is to be welcomed.

PAYS-BAS/ THE NETHERLANDS	The rationale of this article is to be supported. It is however questionable if this is really a realizable aim.
PORTUGAL	Portugal endorses the wording of Article 22.
SUISSE/ SWITZERLAND	Article 22, on transnational practices, requires further reflection as to its scope in an increasingly international science.
TURQUIE/ TURKEY	New formulation: “Any scientific research falling within the scope of this Declaration shall be subjected to ethical review. In cases of international scientific research, ethical review will be made in each of the States involved. States shall ensure that the ethical standards to be applied to the reviews shall not be less than those required by the principles of this Declaration.”

[SPECIFIC ISSUES]

AUTRICHE/ AUSTRIA	Work on the future declaration should focus on elaborating a text that proclaims general principles with concrete subjects to be dealt with in other texts.
BRÉSIL/ BRAZIL	<ul style="list-style-type: none"> - The Brazilian Government would like to add to specific issues a section on bioethics and public health, dealing especially with the right to access to drugs and quality medical care without distinction between the populations of developed and developing countries, and with particular provisions concerning the preservation of the capacity of States to formulate and implement public health policies, more specifically in the event of endemic diseases and pandemics, such as the fight against HIV/AIDS. - In the text, under the heading Specific Issues, the correlations between bioethics and international prohibitions (biopiracy, organ trafficking, and so on) and bioethics and sustainable development should be developed. In this context, the text should refer to the need to prevent the entrenchment of a division of labour prejudicial to developing countries, in which they act in a restricted way as the providers of samples or consumers of drugs and treatments developed on the basis of their genetic heritage and biodiversity, whilst developed countries concentrate in their own hands the knowledge and economic and commercial benefits of their application.
CANADA	It is unclear what this section is intended to address, but it remains the position of Canada that this declaration should not address any specific activity, application or technology that raises bioethical issue.
EQUATEUR/ ECUADOR	<ul style="list-style-type: none"> - Ecuador reiterates its request that the outline to be considered at meetings of IBC and IGBC should restore the subjects listed below that are priorities for many developing countries and without which the Declaration would not have the desired weight and value: - Scientific research, - Research involving human beings, - Health care, - Human reproduction and the beginning of life, - Human reproductive cloning, - End of life, - Organ and tissue transplants, - Genetic data and other personal data concerning health care, - Interventions on germ-line cells, - Gender-based selection, - Pharmacogenetics, - Non-commercialization of the human body and its parts, - Generic drugs, - Right to healthy food - Right to a healthy environment [letter to Board, attached, for the list].
ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	The United States reserves its position on this article until if/when this article is elaborated.

FINLANDE/ FINLAND	This subheading could be deleted.
JORDANIE/ JORDAN	These should be selected carefully to include those involving serious bioethical issues, and to reduce the most serious “drawbacks” of the Declaration, namely, the ambiguity in the frequent reference to “any decision or practice within the scope of this Declaration”.
PORTUGAL	The Declaration as it stands should not contain the section devoted to “Specific Issues”.
ROUMANIE/ ROMANIA	We suggest extending the list of “Specific Issues” to reflect fully the diversity of aspects of life, human behaviour, social developments and scientific discoveries. We therefore propose the following issues: trafficking in human beings, terrorism, ethics in politics and the media, child exploitation, ethics of advertising drugs (concerning the promotion of ineffective or dangerous drugs).
TURQUIE/ TURKEY	In the letter of 11 October 2004, two options were presented on the question of specific subjects. Turkey prefers the second option, if and only if the issues concerning the right to health and scientific research, and especially international scientific research, could be elaborated in their various dimensions connected with the aims of the Declaration. Otherwise, the Declaration should confine itself only to listing relevant issues.
SAINT SIÈGE/ HOLY SEE	With regard to specific issues, and in keeping with the tradition of the International Bioethics Committee, questions and issues already contained in the two adopted declarations should be returned to, without excluding certain relevant issues of functional genetics which have already been studied by the International Bioethics Committee (for instance: <i>genetic counselling, population-based genetics</i> [<i>declaration on human genetic data for first two</i>], <i>genetics and the market (patents), genetics and the family, genetics and international cooperation</i>).

PROMOTION AND IMPLEMENTATION

ALLEMAGNE/ GERMANY	The provisions mentioned in Articles 22 to 25 of the Declaration on the Human Genome should be retained.
CANADA	Consideration should also be given to a provision to encourage States to address bioethics issues even in the absence of full international agreement, along these lines: “It is recognized that general agreement amongst States on the application of the principles of this Declaration to the governance of specific issues with bioethical implications will take time to develop in some cases. Individual States should, nonetheless, undertake effective measures within their jurisdiction to govern such issues in accordance with the principles of this Declaration.”
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	Title: “Promotion and Implementation ”. Declarations are not binding and cannot be “implemented”.

Article 23 - Bioethics education, training and information

BELGIQUE/ BELGIUM	(a) ...These measures should aim at specific audiences, in particular researchers and members of ethics committees, or and be addressed to the public at large.”
BOLIVIE/ BOLIVIA	“a) ... These measures should aim both at specific audiences, in particular researchers and members of ethics committees, or and be addressed to the general public at large.”
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	“a) In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, States should endeavour to foster all forms of bioethics education and training at all appropriate levels as well as to encourage information and knowledge dissemination programmes about bioethics. These measures should aim at specific audiences, in particular researchers and members of ethics committees, or be addressed to the public at large.”

Article 24 - Solidarity and International Cooperation

BOLIVIE/ BOLIVIA	“a) States should respect and promote solidarity towards individuals, families, populations and groups, based on the universal principle of equity and preference for the needs of with special regard for those rendered vulnerable by health or other personal, societal or environmental conditions and those with the most limited resources.”
ETATS-UNIS D’AMÉRIQUE/ UNITED STATES OF AMERICA	<p>“a) States should respect and promote solidarity towards individuals, families, populations and groups, with special regard for those rendered the vulnerable by health or other personal, societal or environmental conditions and those with the most limited resources.</p> <p>b) States should foster the international dissemination of scientific information and make every effort to guarantee the free flow and sharing of scientific and technological knowledge [namely throughout the creation of research and education structures in the developing countries as well as the exchange of knowledge, information, and technical know-how transfer of technology].</p> <p>c) In the framework of international cooperation, States should promote cultural and scientific and medical cooperation among all sectors, and endeavouring to enter into bilateral and multilateral agreements enable developing countries to build up their capacity to participate in generating and sharing scientific knowledge and of the related know-how.</p> <p>There are conditions other than those listed where a person, group, or population can be deemed “vulnerable”. Therefore, we suggest deletion of the specifics of how one is deemed “vulnerable”. Additionally, wouldn’t this subparagraph fit under non-stigmatization and non-discrimination? Finally, what does “solidarity” mean in this context? It should be clarified.</p> <p>States do not have to enter into bilateral and multilateral agreements to help build capacity. Further, the term “know-how” seems a bit colloquial for a document such as this.</p>
JORDANIE/ JORDAN	The word “knowledge” in paragraph (b) to be replaced by “ know-how ”. The sentence in brackets should be kept in [“namely throughout...”].
MEXIQUE/ MEXICO	The sentence in brackets should be kept in [“namely throughout...”].
PAYS-BAS/ THE NETHERLANDS	This article has a rather narrow formulation. Article 6 refers to the solidarity of humanity to ensure equity and encourage international cooperation. In line with this, it would be advisable to change the wording “sharing scientific knowledge” into “sharing knowledge” or into “sharing scientific and traditional knowledge”. This would also be more in conformity with – for instance – the so-called Bonn Guidelines.

Article 25 - Role of States

BELGIQUE/ BELGIUM	“(b) States should establish a framework for the assessment of their actions and management of risks . This framework should include the identification of the issues, the characterization of benefits and risks risks and benefits , the development of options, the implementation of the decisions and the monitoring of results.”
BOLIVIE/ BOLIVIA	<p>“(b) States should establish a universal regulatory framework for the assessment and management of risks. This framework should include the identification of the issues, the characterization of risks and benefits, the development of options, the implementation of the decisions and the monitoring of results, in order to protect each and every nation in an equal manner.</p> <p>(c) Any State or States affected by the failure to comply with this Declaration may make a complaint with a view to correcting or amending the situation.”</p>
DANEMARK/ DENMARK	“(a) ... Such measures should be supported by action in the spheres of education, training and public information, debate and dialogue . States should take appropriate measures that also the younger generations are involved in these activities. ”

<p>ÉTATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA</p>	<p>“a) States should endeavour take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance consistent with domestic and accepted international human rights law principles of human dignity, human rights and fundamental freedoms. Such measures should be supported by action in the sphere of education, training and public information.</p> <p>b) States should establish a framework for the assessment of national bioethical issues and management of risks of scientific and medical research to the health and well-being of individuals or populations. This framework should include the identification of the issues, the characterization of risks and benefits, the development of options, the implementation of the decisions and the monitoring of the results.”</p>
<p>PAYS-BAS/ THE NETHERLANDS</p>	<p>Subparagraph (b) is a very general and sweeping paragraph. It might be reconsidered.</p>
<p>SÉNÉGAL/ SENEGAL</p>	<p>With a view to rendering Articles 23, 24 and 25 easier to understand, and without modifying the arrangement of the provisions contained therein, the idea of grouping these three articles into a single article entitled “Role of States” is worth examining, especially since the actions they describe fall within the competence of States.</p>

Article 26 - Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

<p>BELGIQUE/ BELGIUM</p>	<p>“b) Reports provided by States will be addressed every two four years to the International...”.</p>
<p>CANADA</p>	<p>Serious consideration has to be given to the practical and conceptual challenges of monitoring compliance with a declaratory statement. Further, consideration has to be given to the appropriateness of the roles for the two committees and the attendant resource implications. The provision of reports by States every two years is too onerous, both for the individual States and for the proposed monitoring committee. Serious consideration should be given to not creating a new reporting mechanism for the proposed Declaration.</p>
<p>ÉTATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA</p>	<p>a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall should contribute to the implementation of this Declaration and the the promotion and dissemination of the principles set out therein. On a collaborative basis, the two Committees should be responsible for its monitoring and for the evaluation of its implementation, in particular on the basis of reports provided by States. The two Committees should be responsible in particular for the formulation of any opinion or proposal likely to further the effectiveness of this Declaration. They should make recommendations in accordance with UNESCO’s statutory procedures, addressed to the General Conference.</p> <p>b) Reports provided by States will be addressed every two years to the International Bioethics Committee, which, after having examined them, will give its advice following the statutory procedures of UNESCO. After having examined the advice of IBC and the reports provided by States, the Intergovernmental Bioethics Committee will submit its opinion to the Director-General for transmission, together with the advice and recommendations of IBC, to the Member States, the Executive Board and the General Conference.</p>
<p>JAPON/ JAPAN</p>	<p>It seems irrelevant to ask every country to provide a report automatically every two years? It would be a better solution to ask a report in an appropriate manner, only when necessary. Such regular reports from each country are not requested in the already existing UNESCO Declarations (the International Declaration on Human Genetic Data and the Universal Declaration on the Human Genome and Human Rights).</p>
<p>MEXIQUE/ MEXICO</p>	<p>There are serious doubts as to the control and monitoring mechanisms provided for in Articles 26 and 27. A political declaration of this kind should not establish such mechanisms. Both the monitoring by the Committees referred to, and the requirement of States to report on implementation of the provisions of this Declaration, exceed the intentions of this non-binding future instrument. It is very difficult, not to say wrong, to subject a declaration of ethical principles to implementation mechanisms of a legal nature.</p>
<p>PAYS-BAS/ THE NETHERLANDS</p>	<p>“b) Reports provided by States will be addressed every two five years to the International...”.</p>

Article 27 - Follow-up action by UNESCO

BELGIQUE/ BELGIUM	Belgium is keen to avoid a cumbersome procedure being established under subparagraph (c).
ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	<p>“(a) UNESCO shall should take appropriate action to follow up this Declaration so as to foster progress of the life sciences promotion and dissemination of the principles set out herein and their applications through technologies, based on respect for human dignity and the exercise and observance of human rights and fundamental freedoms.</p> <p>b) UNESCO shall reaffirm its commitment to dealing with all aspects of the biosphere and, if necessary, shall elaborate guidelines and international instruments, as appropriate, on ethical principles related to the environment and other living organisms.</p> <p>c) Five years after its adoption [and thereafter on a periodical basis], UNESCO shall should take appropriate measures to examine the Declaration in the light of scientific and technological development within the context of this Declaration and, if necessary, to ensure its revision, in accordance with UNESCO’s statutory procedures.</p> <p>d) With respect to the principles set forth therein, this Declaration could be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO’s statutory procedures.”</p>
FRANCE	Article 27(b) is a timely contribution to clarifying the scope of the Declaration. Nevertheless, it does not seem essential to reaffirm here UNESCO’s vocation of “dealing with all aspects of the biosphere”, wording that is moreover vague. Defining the competences of agencies of the United Nations system is not the business of a universal declaration of this kind.
JORDANIE/ JORDAN	“(c) Five years after its adoption {and thereafter on a periodical basis}, UNESCO shall take...”.
MEXIQUE/ MEXICO	With regard to the option contained in brackets in Article 27 (c), it would be appropriate and conducive to the due updating of the future declaration.
MONACO	“(a) based on respect for human dignity and the exercise and observance of human rights and fundamental freedoms.”
SUISSE/ SWITZERLAND	“(a) UNESCO shall take appropriate measures to follow up this Declaration so as to foster progress keep pace with the evolution (or development) of the life sciences and their application through technologies, and possible negative effects , based on respect for human dignity, and respect for living beings and the biosphere and the exercise and observance of human rights and fundamental freedoms.”

Article 29 - Restrictions

BOLIVIE/ BOLIVIA	To be deleted.
CANADA	The addition of the bracketed phrase “and necessary in a democratic society” is supported. An additional provision should require that any impairment of the application of the principles be minimal, rationally connected to the risk being addressed and in proportion to the risk.
ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	“No restrictions shall should be placed on the principles set out in this Declaration other than those prescribed by domestic laws and policies . [and necessary in a democratic society]. Such restrictions would be permissible only for important societal interests such as in the interest of public safety, for the prevention of crime prevention, for the protection of public health or for the protection of the rights and freedoms of others.”
FINLANDE/ FINLAND	The addition of the bracketed phrase “and necessary in a democratic society” is supported. This would ensure that the content of the Article corresponds to the requirements of the international human rights instruments adopted by the United Nations and the specialized agencies of the United Nations system.
JORDANIE/ JORDAN	The bracketed phrase “and necessary in a democratic society” should be deleted.

MEXIQUE/ MEXICO	The bracketed phrase “and necessary in a democratic society” should be deleted.
PAYS-BAS/ THE NETHERLANDS	The addition of the bracketed phrase “and necessary in a democratic society” is supported.

Article 30 - Denial of acts contrary to human rights, fundamental freedoms and human dignity

ETATS-UNIS D'AMÉRIQUE/ UNITED STATES OF AMERICA	“Nothing in this Declaration may be interpreted as implying for any States, group or person any claim to engage in any activity or to perform any act contrary to inconsistent with human rights, fundamental freedoms and human dignity, including, in particular, the principles set out in this Declaration.”
MEXIQUE/ MEXICO	Article 30 does not seem to be really necessary, since the breach of normative principles, legal or other, for illicit or immoral purposes is, <i>per se</i> , an illicit act, subject to international accountability, or, an immoral act, worthy of condemnation as such at the political level.

Partie / Part II

ORGANISATIONS INTERGOUVERNEMENTALES / INTERGOVERNMENTAL ORGANIZATIONS

- *Organisation mondiale de la santé (OMS) /
World Health Organization (WHO)*
- *Université des Nations Unies /
United Nations University (UNU)*
- *Conseil de l'Europe /
Council of Europe*
- *Organisation pour la coopération et le développement économiques (OCDE) /
Organization for Economic Cooperation and Development (OECD)*

The comments presented in this document are the written comments from intergovernmental organizations gathered in the framework of the consultation on the Third Outline. In addition, at the fourth meeting of the UN Inter-Agency Committee on Bioethics (Paris, 10 December 2004), the members and associate members of the Committee had the occasion to discuss the Third Outline with Members of the IBC Drafting Group. In this context, further observations and comments were formulated by the organizations that participated in the fourth meeting.

GENERAL COMMENTS

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

The intention of the proposed declaration is not clear: When it asked the Director-General “to continue preparatory work on a declaration on universal norms on bioethics,” the General Conference stated that it was desirable for UNESCO “to set universal standards in the field of bioethics.” Preambulatory Paragraph 6 states that UNESCO has a mission “to develop universal principles and norms” and Paragraph 14 “proclaims the principles.” Yet the IBC’s preparatory work was premised on the broad (universal?) acceptance of certain principles in the field of bioethics, and the human rights norms and principles recited in the perambulatory and operative sections have been extensively elaborated for more than fifty years. Does UNESCO see the task at hand, then, as being to decree something (*i.e.*, “set” and “proclaim”)? That view is consistent with the form chosen, namely a declaration, but would make inappropriate the suggestion that UNESCO has engaged in a process of analysis and elaboration which has led it “to develop” the relevant principles and norms. The latter process would more appropriately lead to a report (such as the 1978 *Belmont Report* or the explanatory material for the Oviedo Convention); it would also have to recognize that the concepts from bioethics and human rights recited in the draft are widely accepted.

The proposed declaration appears inappropriately broad: It is important that UNESCO make clear that this declaration is concerned with “emerging challenges in science,” which the Preamble notes is the Organization’s mission (Preamb. Para. 6), and that it does not attempt to address issues arising in biomedical and public health research or in the provision of health care or the organization of public health, which are within the mission of WHO rather than UNESCO. The line between these two domains is not always sharp, but it exists, as has been recognized since 1948, according to the Agreement between UNESCO and WHO, Art. 1, Para. 2 of which states that “it is recognized by UNESCO that WHO shall have the primary responsibility for the encouragement of research, education, and the organization of science in the fields of health and medicine, without prejudice to the right of UNESCO to concern itself with the relations between pure and applied sciences in all fields, including the sciences basic to health.” The distinction thus is between, on the one hand, UNESCO’s role regarding the sciences (e.g., biology, bioengineering, biotechnology) that underpin health advances and, on the other hand, scientific and educational activities that might otherwise be a matter for UNESCO but which fall within WHO’s ambit because they arise in “the fields of health and medicine.” It is important that the proposed UNESCO declaration be clear on the distinction, since so many “bioethics” topics (from those arising in clinical research to those involved in the provision of health services and the protection of the public’s health) go far beyond “emerging challenges in science” and would not fall under “UNESCO’s activities and programmes ... aiming at placing scientific and technological development in a context of ethical reflection, and at promoting the sustainable use and conservation of biological diversity and the improvement of the relationship between human beings and their environment” (Preamb. Para. 7).

The proposed declaration weakens human rights obligations: The draft appears in many ways to be a “human rights” document (although it is not entirely clear whether the “norms” involved are those recognized in the corpus of international human rights instruments or those developed by scholars and incorporated into professional and governmental documents regarding the ethical conduct of health research and the provision of health services and the protection of the public’s health). Yet the document’s imprecision in stating the relevant human rights principles and norms (as detailed in our comments on the text), along with the absence of any real reporting and monitoring mechanism, undermines its claim to be a human rights declaration.

The activity addressed by the proposed declaration is unclear: A problem that pervades the text—and the one probably most in need to being remedied in subsequent drafts—is the confusion about the activity to which the commandments of the document apply. Reference is made repeatedly to “any decision or practice within the scope of this Declaration” having to be made or carried out under specified principles. In Article 1, the scope of the proposed declaration is said to be “human beings” and “issues raised by scientific and technological developments and their applications”. Does this mean that the declaration applies to all decisions or practices concerning human beings? Probably not, and the solution might lie in incorporating the idea of subsection (i) of Article 1 into (ii) to make clear that the instrument

concerns “issues for human beings” as opposed to “issues for all living beings”; furthermore, it seems unlikely that issues from the physical and chemical sciences are encompassed, so a limitation to the life sciences needs to be added. Even so, this would still leave “any decision or practice [that involves] issues for human beings raised by scientific and technological developments in the life sciences and their applications.” Is it really the intention of the proposed declaration to reach all decisions of all people (as patients, family members, healthcare professionals, government officials, and members of the general public) that relate to the life sciences and their applications in medical practice and public health activities? Limiting the scope to “research in the life sciences” would at least avoid intruding into a myriad of private decisions—and the associated medical practices—where the recited principles become very problematic (*e.g.*, reproduction, care of dying patients, decisions about the use of resources for various health-related purposes). Further ambiguity is introduced in Article 2, where the second bullet point states the aim of ensuring “respect for human dignity and the protection of human rights and fundamental freedoms in bioethical decision making.” What is “bioethical decision making”? Decisions by bioethicists (whoever they may be)? Decisions about bioethics? And is the making of “bioethical decisions” a subset of the decisions or practices “within the scope of this Declaration” or a shorthand expression for those decisions or practices which come within the scope?

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Will this document be, as explained in April at the Extraordinary Session of IBC, an overarching declaration on bioethics within the framework of UNESCO Declaration, including the two already accepted, and the planned Declarations in the area of Ethics of Science and Technology and Bioethics? If this is the intention, then some words to that effect could be inserted either into the preamble, or in Article 26-27?

While there has been insertion of the terms “Biosphere” and “Biodiversity” at points in the text, we would suggest at least one article be included under this heading. For example the issue of “scope” (article 1) could include several articles, because this is a central issue for bioethics and there is widespread customary use of the term for both environmental ethics and medical ethics. A descriptive article would be appropriate to explain what is bioethics.

We propose some concrete suggestions to extend the biodiversity issues, which would give more detailed treatment of environmental ethics issues. We suggest that the issue be dealt with by:

- making reference to relevant environmental treaties in the preamble
- including in the Preamble a section “recognizing the interdependency of humans and the environment, and the fact that bioethics provides the basis for ensuring that this interdependency is respected in order to ensure the highest possible standard of living for humankind within a balanced and sustainable environment.
- expanding the scope to include the impacts of science and technological development on the environment.

The document tends to follow a modern Western-centred approach to bioethics reasoning, and is centred on principlism without reference to virtue ethics. There is room for inclusion of alternative viewpoints on bioethics in future outlines.

The Declaration will be seen to be deficient for a failure to spend time on the issue of animal research. There are some items that could reach consensus, and we encourage the IBC to include an article on the issue as a procedural principle. Many countries already have requirements for ethics committee approval, as do most major scientific journals.

Further consideration is needed throughout the document to the issue of indigenous and local community belief systems and community responsibility versus individual liberty. The issue of indigenous and local community welfare could be reflected specifically in Article 2, 8 and 13. An article promoting traditional knowledge and innovation systems and their role in science and technological development could also be included, as well as commitments to supporting the wider use of such knowledge, with the prior informed consent of indigenous and local communities as a means for securing health and food needs of the global population.

One of the major concerns for the scientific sector and for many developing countries is the impact of intellectual property rights on the global commons. This issue should be addressed in the preamble and in the text of the Declaration by the inclusion of terminology such as the following:

“Recognizing that intellectual property rights has a significant influence on scientific and technological development such rights should be supportive of the principles outlined in this Declaration and not run contrary to them.”

This language could be repeated in the text of the Declaration, perhaps in Article 13. It is based upon similar language in the Convention on Biological Diversity.

**ORGANISATION POUR LA COOPÉRATION ET LE DÉVELOPPEMENT ÉCONOMIQUES (OCDE) /
ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)**

Considering the aims of the declaration, we welcome the decision to re-address under Article 1 the scope and to focus primarily “on the human being”, in line with comments expressed at the recent Hearing of Intergovernmental Organisations organised by the International Bioethics Committee in 2004. We also welcome the explicit recognition in this draft that human beings bear a responsibility towards the biosphere.

We encourage the IBC to achieve similar clarity of purpose under Article 2 on whether the work aims simply to draw a unifying framework from existing universally recognised general principles, or whether it also aims to develop a framework for the provision of basic procedures for the implementation of such principles.

PREAMBLE

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

The order of the materials seems odd, given the unresolved issue of whether the prior UNESCO declarations will be treated as specific subjects under the umbrella of the present document (in which case, the earlier declarations would more suitably come later in the Preamble, as indeed they already do in the penultimate paragraph, “Considering that...”). Giving priority to the UNESCO documents may strike others as unwarranted, given the more fundamental nature of the UN declarations and conventions which now appear in the “Also recalling” paragraph below.

Both in human rights terms and in ethical terms, the commitment to health as a fundamental human right is a bedrock for bioethics. If the proposed declaration is to have broad scope as a human rights and bioethics document, it would there seem appropriate to take note that this right has long been recognized in the UN system, rather than subsuming it within “the other international human rights instruments adopted by the United Nations (etc.).” The point has been made repeatedly by WHO, such as in the Preamble to its Constitution (22 July 1946) and in the World Health Declaration adopted by the World Health Assembly on 16 May 1998 (WHA 51.7), in which WHO’s Member States reaffirm their commitment to “the ethical concepts of equity, solidarity and social justice.” Finally, regarding the last sentence in the paragraph above, is the Doha Declaration a “human rights instrument”? Which other such instruments “adopted by the United Nations and the specialized agencies” are being recalled?

Given the generality of the instruments cited in the second paragraph of the Preamble (many of which have little or no direct bearing on the topic of “bioethics” as addressed in the present declaration), it seems odd not to cite at least the leading declarations and guidelines in this field from groups such as the World Medical Association and the Council for International Organizations of Medical Sciences.

What is the duty in question and in what sense is it “sacred”? It would seem that “all the nations” are the duty-bearers but the reference for “this” would appear to be UNESCO’s obligation to promote democratic principles and reject doctrines of inequality. Thus, the wording suggests that “all nations” have a “sacred duty” to see that UNESCO lives up to its Constitution.

In what sense has UNESCO “developed” the principles and norms recited in this instrument? Previously, the IBC has suggested that the rationale for the present declaration is that certain principles have already come to be widely accepted, not that they need to be developed; were the task of “developing” such principles to be taken seriously, it would seem to require a monograph that would carefully examine the origins of, and justification for, each principle, the relationships among the principles, and so forth.

Doesn’t “respect for and observance of human rights” incorporate “the inherent dignity of the human person” and “fundamental freedoms”? That is, weren’t the many human rights instruments recited in Para. 2 above built on certain premises about human dignity and freedom, to which they have over the past six decades given some very specific legal content? Treating dignity separately from those instruments could prove very mischievous. And which freedoms are “fundamental” as opposed to those that are not?

This paragraph is very difficult to understand; it seems to suggest that cultural diversity is “the common heritage of humanity.” This phrase was ambiguous when the IBC borrowed it previously (from the law of the sea) to describe the human genome; in the present, broader context it is totally opaque. Does this mean that all peoples experience cultural diversity in their lives (i.e., this is the “common” experience of all people)? That would be false. Does it mean that when looked at globally, humankind is culturally diverse? That is true, but it is not apparent what it means to call this our “common heritage” when we each inherit our particular culture, which is not common to all. Nor is it clear how this observation about global diversity relates to the other two thoughts buried in this paragraph, namely that this diversity is “without prejudice to ... human rights” and that this diversity is somehow a necessary source of innovation and creativity. (The latter is plainly wrong; history abounds with homogeneous societies that were creative.) The reader is left with the impression that the lack of clarity reflects the unresolved tension between declaring “universal norms” and wanting to accept local differences demanded by certain cultures, which may contradict those norms.

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There is room for further citations of Declarations from other agencies not only in the field of human rights, but also in a separate paragraph relating to documents agreed upon in the field of environmental issues. This could include mention of the Rio Declaration, the Johannesburg Conference, the World Charter for Nature, and other documents. We would also include reference to the Convention on Biological Diversity, but note that some countries have not signed this.

The Preamble could usefully be strengthened by the inclusion of a number of paragraphs which make reference to:

- The Millennium Development goals and the importance of bioethics and science and technology in meeting these.
- The importance of the traditional knowledge of indigenous peoples and local communities, which plays an important role in human health and food security and is the basis of scientific innovation of a large part of the global population as well as playing an important role in providing the basis for formal scientific research and technological development.
- The importance of ensuring the fair and equitable sharing of benefits derived from scientific and technological development, in particular with developing countries and local communities and indigenous peoples.
- The importance of strengthening and promoting the development of traditional knowledge and innovation systems.

CONSEIL DE L’EUROPE / COUNCIL OF EUROPE

We appreciate the reference to regional texts in the Declaration as it reflects the spirit of collaboration developed by the United Nations and its Agencies with regional organisations and acknowledges their role at international level in the field concerned.

GENERAL PROVISIONS

Article 1 - Scope

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

The first subsection is apparently intended to signal that while “bioethics” is used by some people to encompass non-human life, this Declaration will focus on human beings. Yet, read literally, clause (i) seems to make the instrument applicable to all decisions or practices involving human beings (i.e., virtually all human actions). Likewise, the second subsection seems to take in all fields of science, when principally the life sciences are intended, and to include all applications, which would extend to all of medicine and public health. Ironically, by focusing on “issues raised by ... developments,” clause (ii) leaves out the process of research. Perhaps the subsections should be folded together and narrowed, so that the Article would read “The principles set out in this Declaration apply to research in the life sciences as it affects human beings.” Many of the concerns about lack of clarity and unintended, sweeping consequences that are raised in the comments below would be ameliorated or even eliminated if the scope of the proposed Declaration were restricted to life science research rather than encompassing medical practice, clinical trials, and public health as suggested by the phrase “scientific and technological developments and their applications.”

Article 2 - Aims

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

“...to provide a universal framework of fundamental principles...”: Given the recitation of human rights declarations and conventions, the phrase “a universal framework” seems very weak in that human rights creates explicit obligations on signatories and means of monitoring and enforcement, not simply a “framework.”

“...to recognize the great benefit ... and to prevent practices contrary to human dignity”: Given how ill-defined “human dignity” is outside of human rights instruments, the aim of preventing “practices contrary to human dignity” is especially problematic (witness the three-years of debate in the United Nations over the framework for a treaty to ban human reproductive cloning, even though the Universal Declaration on the Human Genome and Human Rights cites human reproductive cloning as a practice contrary to human dignity.

“...to foster dialogue between scientists, health professionals...”: A declaration sets forth rights and obligations; to foster an intellectual dialogue would require an analytic report.

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New aim: “to ensure the sustainable development of humankind within a balanced environment with due respect for all life forms”.

GENERAL [FUNDAMENTAL] PRINCIPLES

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

It is unclear why or in what sense the principles that follow here (especially Article 5-7) are any more fundamental than those in Articles 8-13, though they may be somewhat vaguer. There is also a very substantial conflict between the human rights-based orientation of some (such as Article 3) and the bioethics basis of others (such as Article 4). Are these principles labelled “fundamental” in the sense that UNESCO feels there is no need to offer justifications for them—that is, they are self-evidently correct and universally accepted?

Article 3 - Human Dignity, Human Rights and Justice

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

As asked previously: why list human dignity as a separate concept from human rights? This is very problematic; for example, if a state were to “adopt” this article, would it then be justified in banning human embryonic stem cell research as a violation of human dignity [because the embryos are destroyed in the process] or would doing so violate human dignity [because living human beings might thereby be deprived of life-extending therapies]? The same question can be asked about “fundamental freedoms” and “justice”—are they not part of human rights? What is implied by listing them separately?

Article 4 - Beneficence and Non-Maleficence

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

This Article exemplifies the problem of the Declaration’s poorly defined scope because it states that “any decision or practice” (presumably including “any decision” made by any patient, family member, physician, etc. or “any practice” in medicine or public health) should optimize benefits and minimize harms. While it may often be prudent for a patient to act in this way, whence comes a duty to maximize benefits to oneself? And what duties are owed to others, whatever their relationship to the actor? Must every decision in research—much less in the practice of medicine—meet these maximize/minimize requirements not only as to the person or persons directly concerned but as to all other persons affected, actually or potentially? For example, does this rule release a physician from his or her ethical obligations to serve only the interests of the immediate patient if doing so would allow more good to be done to others? Read in usual “maximization” terms, this rule seems to add a utilitarian dimension to ethical decisions that is at odds with the requirement of fidelity to the interests of the individual patient. The open-ended nature of the obligation (whose welfare must be taken into account?) would also make it virtually impossible to apply. The final [optional] phrase “to the person concerned” seems intended to bring the principle in line with the heading, but this still begs the question of which persons are concerned with or affected by a decision or practice. For example, the decision of a physician to practice in a private specialty office, rather than in a public clinic, may have profound effects on the distribution of health care in the physician’s community; if it diminishes total welfare, would it be a violation of this principle, meaning that the State would be justified in insisting, or obliged to insist, that the physician practice in the public clinic? The utilitarian language of maximization, etc. in this Article does not fit well under the heading of “Beneficence and Non-maleficence” because those duties are traditionally associated with the Hippocratic obligations of physicians to their individual patients, and by extension, the duties of people in healthcare and research generally to anyone under their care or control. Furthermore, in the context of the individual physician-patient relationship, the goal is not (as the Article states) absolute maximization/minimization but seeking the best ratio of benefits to harms. For example, a patient may undergo a potentially very harmful operation (which does not minimize risk) if that represents, in the view of the patient and her physician, the best means of treating a disease that could have even worse consequences were the operation not undertaken.

Article 5 - Respect for Cultural Diversity and Pluralism

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

This Article seems to want to have it both ways- “taking into account” schools of thought or traditions, etc., that could affect the decisions/practices in question (whatever is encompassed in this category) but without “infringing” upon the universal principles. So, is cultural pluralism itself a universal principle—and if so, how could respect for it infringe on it? The sweep of this Article seems very problematic. For example, it suggests that lying to patients about their diagnosis and prognosis, or performing medical procedures on unmarried adult women based on “consent” received from their brothers rather than themselves, would be acceptable if that reflected a cultural tradition even though it would contradict CEDAW (as well as Articles 11 and 14). Since this Article states a “Fundamental Principle” it would seem

to override such “Derived Principles” as non-discrimination (Article 9), informed consent (Article 11), and privacy (Article 12) as well as “Procedural Principles” such as honesty (Article 14). Finally, even accepting the Article on its own terms, its effect is unclear: whose culture or tradition should be respected when, as is often the case, the people engaged in medical practice or research come from different religions, cultures, traditions, etc.?

Article 6 - Solidarity, Equity and Cooperation

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

This Article mixes two or three very separate principles: nondiscrimination, equity, and solidarity. The first is well established both in bioethics and human rights, though the term “avoid” is weak in the latter context (where “prevent” better describes the obligation of States Parties). In both bioethics and human rights, it is important, however, not to conflate “discrimination and stigmatization” as the Article does. The former is a wrongful act (assuming one is speaking of unlawful discrimination; there are times in medicine and science when it is appropriate, obviously, to make discriminating judgments—indeed, the failure to do so could represent bad science or poor policy), whereas the latter flows from personal beliefs or attitudes, with a variety of consequences of a social and/or psychological nature. Since this Article is not confined to state actors, it is again hard to know what to make of the injunction: individuals shall not regard others (such as people with serious illnesses or disabilities) as “different, or shall not decide to avoid marriage to someone from a family with a history of a genetic disease, because such acts would “stigmatize” them? State-sanctioned discrimination is wrong but it is much harder to see how one can, or should, forbid individual acts that do not deprive a person of his rights but that may amount to a “stigma.” The second principle—equity—is related to, but not quite as clear as, the first. Though it is embodied in bioethics as a requirement for just or fair treatment, it has not been well developed as it applies to individual relationships of physician/researchers and patients/subjects; as regards the obligations of the state, human rights law requires fair treatment of all, especially in the realization of their rights (such as the right to the highest attainable state of health), and this should produce more equitable outcomes. The third principle—solidarity—is even less clear. Who is supposed to “respect the solidarity of humanity” and what sorts of acts would be involved? In the context of individual healthcare decisions or practices, it is especially difficult to regard this principle as anything more than just fine sentiment. Finally, deriving the nondiscrimination obligation from the solidarity and equity principles, makes the obligation contingent and suggests that the entire Article is simply an injunction to rich countries to provide support to poorer ones.

Article 7 - Responsibility towards the Biosphere

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

This Article expresses a noble sentiment but in terms so weak and vague (“due regard”) that it is difficult to imagine any State or individual deriving any guidance from it. Is this simply a weak version of “precaution” (i.e., “keep in mind that your actions may have far-reaching consequences on other living beings”)? In what sense is humankind’s responsibility to the rest of the planet “special”—that is, compared to what? And how should it be weighed in light of the “Primacy of the Human Person” (Article 8)? Does the latter suggest a Biblical view that human beings are God’s highest creation, whose dominion over the world (and role as “co-creators” of that world, in some interpretations) comes with “special responsibility” for other creatures? (If so, what about the majority of humankind for whom the Old Testament is not dogmatically or culturally relevant?) Finally, “their” should be “it” (“any decision or practice”).

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“...for the protection of biodiversity and the biosphere ~~within which human beings exist~~ of which human beings are one species among millions”.

DERIVED PRINCIPLES

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

These principles do not seem different in kind from the preceding ones; moreover, it is not apparent what it means to label them “derived” from those principles.

CONSEIL DE L’EUROPE / COUNCIL OF EUROPE

We would suggest that the title of the fourth chapter: “Derived principles” be reconsidered as it might be perceived as relativising the principles it includes.

Article 8 - Primacy of the Human Person

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

This Article mixes two ideas: that individual interests must prevail over collective interests and that “human persons” are the primary unit of value (as already discussed in the comment to Article 7). The former is a counter-weight to utilitarianism, though the connection between this principle and others (such as Article 4) is unclear, and in the public health realm, it is patently wrong: there are many times when it is legitimate to put the interests of the group ahead of the individual (according, of course, to fair and legitimate legal processes, etc.). The latter meaning—the primacy of human beings, as opposed to other species—seems rather fundamental to the Declaration as a whole, and one of those principles that is simply assumed, rather than “derived.” Moreover, it begs the basic question: what constitutes a “human person” or when does a human being become a “person” or a “person” (in the sense of an individual living entity) become “human”?

UNIVERSITÉ DES NATIONS UNIES / UNITED NATIONS UNIVERSITY (UNU)

If the primacy of the human person is stated in this way then it could be used to justify the pursuit of a persons’ ambitions at the expense of the environment. For example, let us take the case of “sacred groves” in Southern Asia, which are areas of biodiversity preserved for millennia often at the expense of “human persons” who could not enter these havens for utilization of resources. The same concept is extended in many cultures today with national parks. So there is a conflict with it as being derived from article 7. The document makes reference to cultural diversity in the preamble declaring it to be the common heritage of humanity, and in article 5 it says account is to be taken of cultural backgrounds. There is no real recognition of possible divergence of bioethical beliefs with regard to the primacy of the individual over the society. In fact for indigenous peoples and local communities, according to some cultural views individual rights may at times need to be waived in favour of community survival.

Article 9 - Non-Discrimination and non-Stigmatization

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

Some of the remarks made above under Article 6 are applicable here as well: if a prohibited characteristic is used to stigmatize an individual, etc. that either means it is used to treat them unfairly (which is already prohibited by the first clause, on discrimination) or that other people think badly of the individual etc. though they do not mistreat them. Does the Declaration offer any real means of resisting the latter conduct? Part of the difficulty here, as throughout the Declaration, is the passive voice: who are the duty-bearers whose conduct is constrained by this Article—individuals, health care professionals and scientists, governmental officials, or States themselves (in terms of their obligations under human rights conventions to prevent private harms)? A particular issue in using general language about discrimination in the context of health care and research is that there are many generally accepted ways that diseases, etc., are used to separate people into categories and to treat them differently, and it is unclear whether such discrimination is (intentionally or unintentionally) prohibited by this Article.

Article 10 - Autonomy and Responsibility

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

Responsibility is not mentioned in this article. Furthermore, the framework for the proposed declaration is actually Kantian (based on dignity); it would be problematic to introduce now an empirical definition of autonomy (which this one can be interpreted to be), as this will exclude those who are currently not able or free to make decisions.

UNIVERSITÉ DES NATIONS UNIES / UNITED NATIONS UNIVERSITY (UNU)

The title reads “autonomy and responsibility” however the contents are autonomy and liberty. We would suggest the title be “autonomy, liberty and responsibility”, and a second sentence on human responsibility for their moral choices be added.

Article 11 - [Informed] Consent

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

Given the generality of this statement, all the really interesting and difficult questions remain (involuntary treatment of the mentally ill; research on children; withdrawal of treatment from comatose patients; etc.)

CONSEIL DE L’EUROPE / COUNCIL OF EUROPE

On Article 11 on informed consent, we wish to draw attention on the difficulties raised by the request for express consent for any treatment or diagnosis. For example, for a diagnostic physical examination, the need to require express consent as distinct from implied consent could be questioned. Furthermore, the difficulties raised by a consent requirement in emergency situations as well as with persons with severe mental disorder would need to be considered.

ORGANISATION POUR LA COOPÉRATION ET LE DÉVELOPPEMENT ÉCONOMIQUES (OCDE) / ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

Given the complexities of modern genomic science, and the use of information derived from this in subsequent research, the nature of “informed” needs some careful further consideration. The word “express” [Article 11(a)] may be problematic in terms firstly of whether it is stringently interpreted to mean that consent must always be written (impracticable in many cases) and secondly in how this is applied so as to allow use of data in research which by its nature can only be described in the most general terms before it is actually carried out.

Article 12 – Privacy and Confidentiality

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

Imprecision about rights- and duty-bearers is evident again here. This Article would be understandable were it formulated as an obligation of physicians and other professionals and the institutions where they work toward patients or, in most contexts, research subjects; confidentiality has been a bedrock of medical ethics since Hippocrates. But “the persons concerned” is so broad as to encompass all participants as rights-bearers, including not only participants in public health programmes, where privacy may be much constrained, but also the professionals and public health official themselves, whose conduct may be subject to public review or private disclosure (physicians are obliged not to gossip about their patients, but nothing stops patients from gossiping about their physicians!). Moreover, the Article provides no real guidance for the many difficult situations that arise today, such as whether previously collected human biological specimens (such as those stored after biopsies, blood tests, etc.) or hospital records may be used for research purposes without the consent of the people from whom the specimens came or whose care is documented in the records. The phrase “restrictively provided for by domestic law” says nothing (what does “restrictively

provided” mean—that permitted acts are restricted to specified categories? that the categories themselves are as narrow as possible, given a particular goal?). And international human rights law provides no clear guidance for knowing what the relevant rules are (may hospital records be used if the person concerned is dead, on the view that privacy rights are personal and cease upon death? may materials be used if they are anonymized?)

**ORGANISATION POUR LA COOPÉRATION ET LE DÉVELOPPEMENT ÉCONOMIQUES (OCDE) /
ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)**

The inclusion of the word “full” in line 2 of this article seems to us redundant.

Article 13 - Sharing of Benefits

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

The topic of benefit-sharing is one of the most controversial and difficult in bioethics; unfortunately, this Article will not help resolve the issue in any actual cases, not the least because its passive voice expression of the obligation leaves the duty-bearers undefined (individual researchers, research institutions or sponsors, the countries from which they come, the persons who directly benefit from the applications of research, or who?) and the rights-bearers equally vague (“society as a whole and the internationally community”). Ironically, this imprecision contrast sharply with the specificity provided by the list of “benefit forms,” though the latter is in fact a mixed bag, in that subsection (i) refers to a particular group of beneficiaries (research participants), while (ii) to (v) are categories of benefits and (vi) is ambiguous (either an activity, “capacity-building ... for research purposes,” or a benefit, “facilities for building the capacity to design and carry out research”). It may well make sense to spell out expectations that would normally attach when particular types of research—especially late-phase clinical trials—are conducted by researchers and sponsors from one [resource-rich] country in another [resource-poor] country, but the Article as written seemingly extends far beyond that to the results of all scientific research and development. The usual view of obligations in the latter context is that they are either controlled by contracts (for example, obligations of researchers to make available the results of studies conducted with public funds) or by intellectual property law, which provides the holders of such property rights with monopoly benefits in exchange for the disclosure of their methods and means. Does the Declaration intend to alter this arrangement by creating new rights? It is instructive to contrast this generality with the greater specificity achieving in the Doha Declaration, which recognizes that determinations concerning health needs can override usual intellectual property rights and which led to the WTO’s August 2003 agreement regarding the circumstances in which states that lack manufacturing capacity for vital patented drugs can obtain them from other countries where they are produced under compulsory licenses. Likewise, a number of bioethics bodies (e.g., Nuffield Council on Bioethics; U.S. National Bioethics Advisory Commission) have proposed standards and procedures for researchers and sponsors to reach advance agreement with research participants and host country officials about the circumstances in which certain benefits will be provided following a research project. The World Medical Association has, however, been unable to reach a resolution over the past two years on the contentious question raised by the Declaration of Helsinki of what obligations are owed to continue providing experimental interventions to research participants “at the conclusion of the trial.” There is plainly need for more attention to the issue of “benefit-sharing,” yet this need is not met by the vague, general language of this Article.

UNIVERSITÉ DES NATIONS UNIES / UNITED NATIONS UNIVERSITY (UNU)

This is an excellent article. In the principle of biocentric bioethics we would also suggest a new item, before the existing vii) to read: “*vii) sharing benefits of research for the welfare of non-human species who contributed to the research*”.

PROCEDURAL PRINCIPLES

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

The term “Procedural Principles” could connote two things. First, it might mean principles for discourse about bioethics and would extend to the IBC’s own role. Second, it could aim at the undefined actors who are to be governed within whatever “decisions and practices” come within the scope of the declaration. Since the latter seems to be the intent, it is a shame that the basis on which this group of principles is separated from those in the previous two sections is unclear and on its face unpersuasive. Other than Article 18, none of these Articles seem any more or less “Procedural” than many of the others. For example, in what sense are the obligations to act honestly (Article 14) or transparently (Article 15) or to follow scientific methods (Article 16) or to consult with members of relevant disciplines (Article 17) any more matters of procedure than the obligations to act justly and respect human rights (Article 3), to obtain informed consent (Article 11), to protect confidential information (Article 12), or to share benefits (Article 13)? Rather, they all embody an implicit substantive goal combined with means for achieving that goal.

Article 14 - Honesty and Integrity

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

The role of “independence” is unclear both because the actor who should be independent (a scientist? a physician? a patient or subject? a health minister?) is not specified and the person or organization from whom this actor is supposed to be independent is also undefined. Plainly, some of the actors involved in research and, even more so, health care and public health, have obligations not to act independently—they must act in accordance with rules and obligations to persons or organizations. One of the central tasks of ethics, from the time of Hippocrates, has been to address the conflicts that arise when a professional is in some sense not fully independent. For this reason as well, it is not always clear that conflicts of interest can be avoided as stated here, though in many circumstances, there will be a duty to mitigate their effects. The final clause is too vague for one to know what sorts of “knowledge” (the existence of a “decision or practice” or detailed facts about it?) have to be shared with whom. Would this encompass everything from publishing the results of research (“share knowledge ... with ... the scientific community”), to altering advocacy groups to the possible implications of new findings, to the obligation to disclose information to patients in the course of obtaining their informed consent for a medical procedure? If the answer is “yes, all of the above,” then it can be said that this sweeping statement is certainly not clear on all of these obligations and that they cannot possibly rest on the same ethical premises and hence it is odd to lump them together.

CONSEIL DE L’EUROPE / COUNCIL OF EUROPE

Concerning item iii) of Article 14, while recognising the need to avoid conflicts of interest, we think that conflicts of duty might be unavoidable in certain cases in medical practice, such as in genetic testing with the duty to respect private life of the person concerned and the duty to protect the health of his or her family members when results are relevant to them.

Article 15 - Transparency and Openness

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

The same sorts of concerns as those expressed concerning Article 14 arise here, as the justifiability of such duties would vary so greatly depending on the actors to whom they apply in differing circumstances. It would also be helpful to acknowledge the tension between (i) on transparency and (iii) on privacy and (iv) on scrutiny, rather than simply reciting these points separately. Finally, what is meant by “susceptibility” to public debate?

Article 16 - Scientific and Rational Methods

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

Since the Article specifically notes the “possibility of exceptions,” it would be helpful to be offered some reference point for what constitutes a valid basis for making an exception. The only point mentioned is individuality. In the context of scientific rigor, is the suggestion that some people or practices fall outside of scientific methods (they are not subject to the laws of nature?) or individuals should be free to disregard evidence when it comes to decisions about themselves? About their communities? Or, if they are scientists, about their research projects? What sorts of things can they disregard on individual grounds—information about costs vs. benefits, or about risks, or what? Finally, what does it mean under (ii) to “pay due regard to any different information”? Different than what?

Article 18 - Fair Decision-Making Process

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

WHO places great store in “fair processes” (see, for example, our recent guidance document for equitable access to treatment for HIV/AIDS). Outside the health-systems context, however, it is not exactly clear what would constitute “fair procedures” in research design or implementation nor in what ways medical decisions should be subject to “full and free discussion.”

PROCEDURES

Article 19 - Risk Assessment

UNIVERSITÉ DES NATIONS UNIES / UNITED NATIONS UNIVERSITY (UNU)

Article 19 should be strengthened to reflect the precautionary principle. This is important, and already has broad international legal agreement. To this end the words “scientific evidence” should be deleted in the first line. When there is a threat of serious or irreversible damage to public health and human, appropriate measures should be taken to mitigate any potential harm, even where there is no detailed or specific scientific evidence. Waiting for scientific evidence that is acceptable to all may lead to irreversible harm, and what is considered “scientific” is not always clear. In addition human welfare should be intended in a holistic sense.

Article 20 - Ethics Committees

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

Since “the scope of this declaration” remains undefined, one cannot tell whether this provision would insist on ethics committee only for biotechnology research or more broadly, perhaps for all clinical encounters (which are certainly encompassed within “bioethics” but for most of which—especially in outpatient settings—no ethics committees now exist, nor is it self-evident that they would be desired by patients or tolerated by professionals, much less the question of who would appoint and support them). One of the arguments for local ethics committees, both in research centres and in hospitals, is that they can bring to bear local or institutional values; in this sense their representation of particular or even parochial rather than pluralistic views is regarded as a virtue, which this Article seems to reject.

Article 21 - Ensuring Public Debate

**ORGANISATION MONDIALE DE LA SANTÉ (OMS) /
WORLD HEALTH ORGANIZATION (WHO)**

Like the other Articles in this section, this one is not tied to any “decisions or practices,” so its injunction that states should ensure informed public debate invites the question “how, when, and about what?”

[SPECIFIC ISSUES]

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

If specific issues are mentioned, one assumes they will be limited to matters of biotechnology and not encompass the long list of topics in medical care, public health, health systems, and clinical research set forth in the IBC's invitation for public comments earlier this year.

CONSEIL DE L'EUROPE / COUNCIL OF EUROPE

Based on our experience at regional level, we consider that it might be difficult to define such norms on specific subjects in the very limited time allowed by the timetable approved by the Executive Board. We appreciate therefore the proposals made by the Drafting Group with regard to specific issues and wish to stress the importance of an international text proclaiming principles based on fundamental values in the field of bioethics.

PROMOTION AND IMPLEMENTATION

Article 24 - Solidarity and International Cooperation

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

Art. 24 b): *This* objective is, of course, the subject of many WHO activities and publications, such Genomics and World Health (2002) and World Report on Knowledge for Better Health (2004).

Article 26- Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

This Article suggests that the IBC and IGBC will function both as “treaty-monitoring bodies” and as supreme advisory bodies on specific “bioethics” topics beyond those addressed directly in the proposed declaration. While it is certainly appropriate for UNESCO to evaluate the effects of the declaration, the apparent comparison to a treaty monitoring role (based on States' obligation to submit reports on their implementation of the declaration) seems odd, since the instrument does not have the status or formality of a treaty. The open-ended nature of the advice that these UNESCO bodies may provide is also problematic, given the ill-defined scope of the document.

Article 27 - Follow-up action by UNESCO

ORGANISATION MONDIALE DE LA SANTÉ (OMS) / WORLD HEALTH ORGANIZATION (WHO)

The concerns expressed regarding Article 26 apply to subarticle (d), unless the assurance of “accordance with UNESCO's statutory procedures” implies accordance with UNESCO's constitutional objectives and its long-standing agreement with WHO regarding their respective responsibilities.

ORGANISATION POUR LA COOPÉRATION ET LE DÉVELOPPEMENT ÉCONOMIQUES (OCDE) / ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

Article 27 (c) - Given the rapid advance of science, it is important to ensure a process is in place to keep pace with developments. Therefore we suggest that the word [and thereafter on a periodical basis] in brackets should be included as well as an indication of a timeframe for subsequent review.

Partie / Part III

ORGANISATIONS NON GOUVERNEMENTALES / NON-GOVERNMENTAL ORGANIZATIONS

- *Association asiatique de bioéthique / Asian Bioethics Association*
- *Association médicale canadienne / Canadian Medical Association*
- *Center for Cognitive Liberty & Ethics (USA)*
- *Conseil des organisations internationales des sciences médicales / Council for International Organizations of Medical Sciences (CIOMS)*
- *Conseil international des femmes / International Council of Women*
- *Fédération internationale des femmes des carrières juridiques*
- *Fédération internationale des universités catholiques (FIUC) / International Federation of Catholic Universities*
- *Fédération mondiale des travailleurs scientifiques (FMST) / World Federation of Scientific Workers (WFSW)*
- *Inclusion International*
- *Office international de l'enseignement catholique (OIEC) / Catholic International Education Office*
- *SIDA information Suisse / AIDS Information Switzerland*
- *Société internationale de bioéthique (SIBI) / International Society of Bioethics*
- *The Human Genetics Commission (HGC), The Medical Research Council (MRC), the Royal College of General Practitioners (RCGP) and the Wellcome Trust*
- *Union mondiale des organisations féminines catholiques*

GENERAL COMMENTS

ASSOCIATION ASIATIQUE DE BIOÉTHIQUE / ASIAN BIOETHICS ASSOCIATION

We would like more discussion of the terms “Biosphere” and “Biodiversity” in devoted articles. The interdependency of humans and the environment should be noted.

A descriptive article would be appropriate to explain what is bioethics.

The document follows a modern Western-centred approach to bioethics reasoning, and is centred on principlism without reference to virtue ethics. Please consider the inclusion of alternative viewpoints on bioethics in future outlines, including community-based perspectives for consideration of bioethics.

Further consideration of indigenous and local community belief systems and community responsibility versus individual liberty. The issue of indigenous and local community welfare could be reflected specifically in Articles 2, 8 and 13.

The Declaration will be seen to be deficient for a failure to spend time on this issue. There are some items that could reach consensus, and we encourage the IBC to include an article on the issue as a procedural principle. Many countries already have requirements for ethics committee approval, as do most major scientific journals.

ASSOCIATION MÉDICALE CANADIENNE / CANADIAN MEDICAL ASSOCIATION

The Declaration is thoughtful, insightful and well written. The cited fundamental and derivative principles are consistent with the Canadian Medical Association’s and other health care professionals Codes of Ethics.

FÉDÉRATION INTERNATIONALE DES UNIVERSITÉS CATHOLIQUES (FIUC) / INTERNATIONAL FEDERATION OF CATHOLIC UNIVERSITIES

La FIUC félicite le Groupe de rédaction mis en place par le Comité international de bioéthique de l’UNESCO pour cette troisième ébauche de texte sur une déclaration relative à des normes universelles en matière de bioéthique.

FÉDÉRATION MONDIALE DES TRAVAILLEURS SCIENTIFIQUES (FMTS) / WORLD FEDERATION OF SCIENTIFIC WORKERS (WFSW)

Les principes formulés dans la troisième ébauche de déclaration n’entreront, progressivement, dans la vie que si l’on agit également sur le contexte économique. C’est ce qu’évoque le 2e considérant en mentionnant les ADPIC ; l’OMC et la déclaration de Doha. L’article 24 relatif à la solidarité et à la coopération internationale et le 25 relatif au rôle des États, situent certains niveaux de responsabilités à cet égard. Nous souhaitons vivement que cela soit explicité plus clairement et plus complètement.

INCLUSION INTERNATIONAL

The Third Outline of a Text on Universal Norms on Bioethics (August 2007) provides a strong foundation for international standards for consideration of bioethical issues which are important to people who have an intellectual disability and their families. Both the General (articles 3-5) and Derived (articles 8-10) Principles can certainly be understood to include and protect the human rights of people with intellectual (and other) disabilities.

OFFICE INTERNATIONAL DE L’ENSEIGNEMENT CATHOLIQUE (OIEC) / CATHOLIC INTERNATIONAL EDUCATION OFFICE

1. Le terme « norme » nous semble ambigu : peu ou pas contraignant pour les pays anglo saxons, il est en revanche profondément ancré dans la tradition juridique française.
2. Le texte ne fait pas mention de la société civile.
3. Il nous semble nécessaire d’insister davantage sur les bienfaits de la science.

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

The truly philosophical declaration is, obviously, a product of western thinking. The danger therefore exists that it will not be globally accepted and understood, despite the “Respect for Cultural Diversity and Pluralism” stated in Article 5. It should carefully make sure that the principles grasp the common core of cultures and religions (christian, islamic, jewish, buddhistic, hinduistic, shintoistic and others). Probably, the paper will then be very short.

According to the accompanying letter, dated October 11, 2004, the declaration is focused primarily on the human being. We are afraid that this position is insufficient. The largest extinction phenomenon is now taking place since 65 Mio years described by zoologists, botanists, ecologists and biologists. It is mainly man-made, and education concerning the behavior towards the whole living world is of highest priority. Conservation and sustainable use of animals, plants, atmosphere, water and reserves is retroactive on mankind with respect to survival, morals and ethics. We are fully convinced that the daily brutalities against the extrahuman biosphere from bull-fight to overfishing, but also in games and media are incompatible with human dignity, responsibility, honesty and integrity and that there is a direct connection between the disregard of the biosphere and crimes such as the Ruandan genocide. It is mandatory to dismiss the anthropocentric position and to protect all forms of life. We urgently encourage the committee to stress these vital connections more than indicated in the ingress, being aware that such a courageous position touches economic interests and traditions.

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

The consultation letter suggests 2 options for the way in which specific subjects should be dealt with in the text of the declaration. We suggest that the first option is the most appropriate approach and that the Declaration should be confined to defining high level principles rather than focus on specific topics or areas in bioethics. We believe that this is essential in order to achieve the greatest level of consensus between member states and to ensure that the Declaration represents commonly agreed standards which remain flexible to legitimate differences in moral outlook between member states. This would enable it to be consistent with Article 5 (Respect for Cultural Diversity and Pluralism).

TITLE**OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) / CATHOLIC INTERNATIONAL EDUCATION OFFICE**

Plutôt que « déclaration relative à des normes universelles », nous souhaitons une *Déclaration universelle relative à des normes...*

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Declaration on Bioethics”.

PREAMBLE**ASSOCIATION ASIATIQUE DE BIOÉTHIQUE / ASIAN BIOETHICS ASSOCIATION**

There is room for further citations of Declarations from other agencies not only in the field of human rights, but also in a separate paragraph relating to documents agreed upon in the field of environmental issues. This could include mention of the Rio Declaration, the Johannesburg Conference, the World Charter for Nature, and other documents. We would also include reference to the Convention on Biological Diversity.

FÉDÉRATION MONDIALE DES TRAVAILLEURS SCIENTIFIQUES (FMTS) / WORLD FEDERATION OF SCIENTIFIC WORKERS (WFSW)

7e considérant : Le terme « perspective » (3èm ligne) peut avoir une double signification : soit il exprime l'idée du futur, un but vers lequel on tend, soit il précise le point de vue, l'angle sous lequel on étudie une question. Le premier sens (le futur) suggère que l'inscription du

développement scientifique dans une réflexion éthique se fera plus tard. Cela ne nous paraît pas être l'idée qu'ont voulu exprimer les rédacteurs du texte. La réflexion éthique existe déjà. Elle a de nombreux acquis à son actif. Nous voulons inscrire le développement scientifique dans ce contexte ou ce cadre. L'utilisation du terme « contexte » ou du terme « cadre » éviterait la confusion.

11e considérant : Nous sommes réservés sur la formulation « ...*la réflexion éthique fait partie intégrante du développement scientifique et technologique...* ». Nous partageons évidemment la conviction que cette réflexion doit accompagner l'activité scientifique, qu'elle doit être rigoureuse et que, en ce sens, on ne peut accepter qu'une activité scientifique se développe sans un effort parallèle sur le plan éthique. Nous comprenons également que l'éthique soit considérée comme une science au sens des sciences humaines et sociales. Mais nous ne voudrions pas que soit accréditée, dans l'opinion générale, c'est-à-dire parmi les non scientifiques, l'idée que la réflexion éthique serait une science à côté de la biologie ou à côté d'autres disciplines scientifiques. Cette idée existe. Elle est un obstacle au débat sur les enjeux sociétaux soulevés par les progrès de la biologie et des sciences en générale car elle est alors tenue pour une affaire de scientifique, de spécialistes. Nous préfererions une formulation telle que « *Convaincue que la réflexion éthique doit accompagner le développement technologique et que ...* ».

**OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) /
CATHOLIC INTERNATIONAL EDUCATION OFFICE**

« Consciente que les êtres humains (...) des devoirs **les uns à l'égard des autres et aussi à l'égard des autres formes de vie,**

Reconnaissant que les progrès(...) et dans le respect universel **effectif,**

Convaincue que la réflexion éthique (...) dans les choix sociaux, **politiques et économiques** qu'il convient de faire... ».

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Recordando también el Convenio para la Protección de los Derechos Humanos y la Dignidad del Ser Humano ... (o **Convención de Asturias de Bioética**) que fue aprobado en 1997 y entró en vigor en 1999, **así como su Protocolo de 1998 prohibiendo la clonación reproductiva,** y los demás instrumentos...,”

Considerando asimismo que la UNESCO tiene por misión elaborar principios y normas universales [**elaborar propuestas de conductas universales**] basadas...,”

Teniendo presente que las actividades y programas de la UNESCO ... y a promover una utilización y conservación sostenibles de la [**naturaleza, el medio ambiente y la**] diversidad biológica, así como una mejor relación [**para una adecuada relación**] entre los seres humanos y su entorno [**vital**],

Consciente de que los seres humanos forman parte integrante de la biosfera y que tienen responsabilidades y deberes para con las demás formas de vida [**y el medio ambiente**]

Considerando la Bioética como “**el campo multidisciplinar e intercultural del conocimiento que se implica desde perspectivas éticas -de forma comprometida, social, práctica, y a ser posible anticipadamente-, en el análisis de la ciencia y la tecnología y su repercusión sobre la vida en general, y especialmente sobre la vida humana, con el propósito de orientar a que sirvan de forma efectiva a todos los seres humanos, de contribuir a la resolución correcta de los problemas que se derivan o puedan hacerlo de ellas, y de ayudar a impedir su uso abusivo**”.

Convencida de que la reflexión ética forma parte integrante del progreso científico y tecnológico y de que la Bioética, [**generadora de orientaciones asentadas en valores, debidamente informadas y acreditadas y guía de conductas o prácticas**], desempeña hoy un papel fundamental en las opciones sociales que es menester efectuar,

Considerando que las cuestiones de Bioética suscitadas por [**los conocimientos ya consolidados y acumulados y**] los adelantos de la ciencia y tecnología [**por la ciencia y la tecnología y sus aplicaciones**] y abordadas en parte tanto...”.

GENERAL PROVISIONS

Article 1 - Scope

FÉDÉRATION INTERNATIONALE DES UNIVERSITÉS CATHOLIQUES (FIUC) / INTERNATIONAL FEDERATION OF CATHOLIC UNIVERSITIES

La FIUC se réjouit du choix du CIB de développer un texte qui a trait d'abord à l'être humain, tout en affirmant ses responsabilités et ses devoirs envers d'autres formes de vie de la biosphère.

OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) / CATHOLIC INTERNATIONAL EDUCATION OFFICE

« (i) *aux êtres humains (...)* **les uns à l'égard des autres** et des autres formes de la vie;
... (iii) **à la question de l'éducation à la bioéthique.** »

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“~~Los principios enunciados~~ **Las conductas bioéticas enunciadas** en la presente Declaración se aplican a:

- (i) los seres humanos, en el entendimiento de que éstos tienen responsabilidades y obligaciones para con las demás formas de vida de la biosfera y **el medio ambiente, ...**”.

Article 2 - Aims

ASSOCIATION ASIATIQUE DE BIOÉTHIQUE / ASIAN BIOETHICS ASSOCIATION

An extra paragraph in article 2 to specify that the aims of the Declaration could include: “*to ensure the sustainable development of humankind within a balanced environment with due respect for all life forms*”.

FÉDÉRATION MONDIALE DES TRAVAILLEURS SCIENTIFIQUES (FMTS) / WORLD FEDERATION OF SCIENTIFIC WORKERS (WFSW)

« (iv) de reconnaître les grands bienfaits qui ~~découlent~~ **peuvent découler** des sciences et des technologies, ~~tout en faisant en sorte que~~ **dès lors que** ces progrès s'inscrivent... ».

OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) / CATHOLIC INTERNATIONAL EDUCATION OFFICE

« - de fournir un cadre universel (...) visant à guider **par ce référent** les Etats dans **l'élaboration** de leur législation...

- de reconnaître les bienfaits (...) dans le cadre de principes éthiques qui respectent la dignité humaine, protègent les droits de l'homme, les libertés fondamentales et **empêchent** les pratiques contraires à la dignité **de l'homme et de la femme**
- d'encourager le dialogue (...) les décideurs et l'ensemble de la société **civile** de sauvegarder les **besoins** des générations présentes et futures ».

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Los objetivos de la presente Declaración son:

- proporcionar un marco universal de ~~principios~~ **orientaciones** fundamentales y ~~procedimientos~~ **conductas, practicas** básicas para orientar a los Estados en la formulación de sus legislaciones y políticas en el ámbito de la Bioética, y servir de base para dar a las instituciones, agrupaciones y personas interesadas **y a la sociedad en general** orientaciones en materia de Bioética;
- ...
- promover el respeto de la biodiversidad, **a la naturaleza y al medio ambiente**

- reconocer los beneficios considerables que emanan del progreso de la ciencia y la tecnología, velando al mismo tiempo por que ese progreso se realice en el marco de los principios éticos que respetan la dignidad humana y protegen los derechos humanos y las libertades fundamentales, e impedir las prácticas contrarias a la dignidad humana o **susceptibles de causar riesgos desproporcionados**;
- fomentar **las deliberaciones** y el diálogo entre científicos,...
- **promover la enseñanza de la Bioética en todos los niveles educativos**;
- **promover la información veraz y puntual a la sociedad y a deliberación sobre esa información, principalmente a través de debate público**;
- salvaguardar los intereses **de nuestra especie** y de las generaciones presentes y venideras.”

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

The wording separates out the “sharing of knowledge concerning scientific and technological developments” from the “sharing of benefits”, which suggests that the former is not a form of benefit. We would therefore suggest re-phrasing the article as follows: “... *to promote benefit sharing, in particular with developing countries, including the sharing and the greatest possible flow of knowledge concerning scientific and technological developments*”.

GENERAL [FUNDAMENTAL] PRINCIPLES

FÉDÉRATION INTERNATIONALE DES UNIVERSITÉS CATHOLIQUES (FIUC) / INTERNATIONAL FEDERATION OF CATHOLIC UNIVERSITIES

Compassion should be considered.

OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) / CATHOLIC INTERNATIONAL EDUCATION OFFICE

Suggestion pour le titre de la section : « Principes **fondamentaux** ».

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

Suggestion for the headings: “**Derechos Fundamentales**”.

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

For logical reasons, it is more appropriate to call this section heading “General” rather than “Fundamental” principles. Given that Article 5 (Respect for Cultural Diversity and Pluralism) is a qualified principle, it cannot strictly speaking be said to be a “fundamental” principle.

Article 3 - Human Dignity, Human Rights and Justice

CENTER FOR COGNITIVE LIBERTY & ETHICS (CCLE)

“Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms, **including freedom of thought**, and for the universal principle of justice **as set forth here and in the UN Declaration of Human Rights.**”

FÉDÉRATION INTERNATIONALE DES UNIVERSITÉS CATHOLIQUES (FIUC) / INTERNATIONAL FEDERATION OF CATHOLIC UNIVERSITIES

Concerns have been expressed towards “respect for life” which is not mentioned.

**OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) /
CATHOLIC INTERNATIONAL EDUCATION OFFICE**

« ...devoir de promouvoir le respect universel **effectif** (...) et en conformité avec les principes universels **de justice** ».

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

In German there are two different meanings of the term “human dignity”. On one side, human dignity is perceived as inborn; it is a juridical construct stating that a (human) being may not be violated or misused in any way. The term is difficult to define; it stipulates a gift. On the other side, human dignity is acquired by incontestable behavior; it can be lost even in old age by bad behavior irrespective of former merits. With this conception not all human beings are equal or equivalent. Thus, the term of inherent dignity is a term not without dangers: it can not be defined, it can easily be misused and it can not produce good examples. (The notions demonstrate the intricacies of terms even within the indoeuropean languages!)

Accepting the term as describing an inborn gift implies that it can not be relativated. The declaration of (human) rights endowes then all (human) life with equal dignity from fertilization to natural death, whether born or unborn, whether disabled or “normal”. For example, the apprehension that (human) dignity is slowly increasing from the beginning to extrauterine life in order to justify abortion, is a mere sophism.

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

New title: “Dignidad humana y demás derechos humanos y libertades fundamentales”

**THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC),
THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST**

We suggest that a “universal principle of justice” is an ambiguous concept and suggest clarifying the article as follows: “*Any decision or practice ... for the inherent dignity of the human person, human rights and fundamental freedoms ~~and for the universal principle of justice~~ which encapsulate universal aspects of the principle of justice*”.

Article 4 - Beneficence and Non-Maleficence

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Toda decisión o práctica que entre en el ámbito de la presente Declaración deberá **acompañarse de garantías para** ~~tratar de~~ optimizar [incrementar al máximo] sus efectos beneficiosos, **prever sus posibles riesgos** y reducir al mínimo sus eventuales efectos nocivos [para las personas interesadas] **para las personas, la especie, futuras generaciones y la biosfera**”.

**THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC),
THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST**

“Any decision or practice within the scope of this Declaration shall seek to **optimize** the benefits and minimize the possible harms of such decision or practice **both to the individuals concerned and to society as a whole.**”

Article 5 - Respect for Cultural Diversity and Pluralism

CENTER FOR COGNITIVE LIBERTY & ETHICS (CCLE)

“Any decision or practice within the scope of this Declaration [...]. However, **cultural diversity** shall not be invoked to infringe upon, **nor limit the scope of** the universal principles set out in this Declaration **and as set out in the UN Declaration of Human Rights.**”

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Toda decisión o práctica que entre en el ámbito de la presente Declaración deberá tener en cuenta los contextos culturales, doctrinas, sistemas de valores, tradiciones históricas y filosóficas, creencias religiosas y otras consideraciones de ~~esta índole~~ **de índole semejante...**”.

**THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC),
THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST**

The term “universal principles” is not used elsewhere in the Declaration and we suggest that in order to clarify exactly which principles act as a qualification on article 5 the final sentence should read: *“However, different practices arising from cultural diversity shall not be invoked to infringe upon the other general principles set out in this Declaration, nor to limit their scope”*.

Article 6 - Solidarity, Equity and Cooperation

**OFFICE INTERNATIONAL DE L’ENSEIGNEMENT CATHOLIQUE (OIEC) /
CATHOLIC INTERNATIONAL EDUCATION OFFICE**

« Toute décision ou pratique (...) de la solidarité **entre les hommes**, afin de **proscrire toute** discrimination et stigmatisation **frappant** un individu, une famille ou un groupe **afin d’assurer** l’équité (...) la coopération. »

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Toda decisión o práctica que entre en el ámbito de la presente Declaración deberá respetar la solidaridad de la humanidad, garantizar la **justicia y la** equidad y fomentar la cooperación internacional [para evitar, entre otras cosas, que un individuo, familia o grupo sean discriminados y estigmatizados].”

Article 7 - Responsibility towards the Biosphere

ASSOCIATION ASIATIQUE DE BIOÉTHIQUE / ASIAN BIOETHICS ASSOCIATION

The end of this article could be changed from “within which human beings exist” to “of which human beings are one species among millions.”

**FÉDÉRATION INTERNATIONALE DES UNIVERSITÉS CATHOLIQUES (FIUC) /
INTERNATIONAL FEDERATION OF CATHOLIC UNIVERSITIES**

La responsabilité particulière des êtres humains est certes des protéger la biodiversité et la biosphère dans lesquelles ils vivent. C’est aussi d’exercer leur créativité en recourant à des moyens qui respectent la finalité de notre environnement et de notre humanité.

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

“Within which human beings exist” should be cancelled; the biosphere englobes the deep sea and the atmosphere in which human beings do not exist.

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Toda decisión o práctica que entre en el ámbito de la presente ... a la protección de la biodiversidad y la biosfera en la que viven, **de cuya conservación adecuada y sostenible depende su existencia y la de generaciones futuras.**”

DERIVED PRINCIPLES

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

Title: ~~Principios~~ **Conductas** Derivado[a]s”.

Article 8 - Primacy of the Human Person

ASSOCIATION ASIATIQUE DE BIOÉTHIQUE / ASIAN BIOETHICS ASSOCIATION

If the primacy of the human person is stated in this way then it could be used to justify the pursuit of selfish ambitions at the expense of the environment. According to some cultural views individual rights may at times need to be waived in favour of community survival.

FÉDÉRATION INTERNATIONALE DES UNIVERSITÉS CATHOLIQUES (FIUC) / INTERNATIONAL FEDERATION OF CATHOLIC UNIVERSITIES

L'article 8 affirme clairement la primauté de la personne humaine. Et cela est fort apprécié. Mais qui peut être qualifié de personne? Nous savons que le Groupe de rédaction n'a pas voulu entrer dans le débat de la définition de la personne ou encore que cette définition est réservée pour la section des définitions. Il serait bon cependant de souligner la nature sociale de la personne humaine. Cette valeur fondamentale rappelle l'interdépendance de chaque personne avec les autres êtres humains et avec toute la création. En lien avec la personne, il serait peut-être approprié de rappeler la valeur du corps et du principe de son respect, ce qui signifie non chosification, inaliénabilité et indisponibilité.

FÉDÉRATION MONDIALE DES TRAVAILLEURS SCIENTIFIQUES (FMTS) / WORLD FEDERATION OF SCIENTIFIC WORKERS (WFSW)

D'une part, il nous semble préférable de souligner que c'est seulement lorsque la science ou la société ont des intérêts qui mettent en question ou affaiblissent la reconnaissance à la primauté de la personne humaine, qu'il faut affirmer la primauté de la personne humaine. En conséquence nous pensons qu'il est important d'inclure le terme « **seul** » dans cet article.

D'autre part, la question de la primauté n'a pas le même contenu selon qu'on oppose la personne humaine au *seul intérêt de la société*, ou qu'on oppose la personne humaine au *seul intérêt de la science*. Et, à vrai dire, seule la deuxième opposition nous paraît relever du projet en cours d'élaboration. Presque tous les grands projets du développement humains reconnaissent l'existence d'une contradiction entre la personne humaine et *l'intérêt de la société*. Cette contradiction ou ce conflit d'intérêts ne sont pas résolus par la seule référence à la notion de primauté de la personne humaine, sauf à considérer qu'ici, la personne humaine ne désigne plus un individu mais un groupe, une portion d'humanité.

Une particularité de la biologie est que l'objet des recherches peut aussi être un sujet (la recherche en reproduction humaine, notamment). C'est ce qui appelle la mise en place de garde-fous. Ce qui, nous semble-t-il est recherché par le texte en cours d'élaboration, et que nous approuvons, c'est de donner une assise élargie à ce qui est déjà condamné par des instruments antérieurs, à savoir les recherches comportant des expérimentations sur l'être humain, ou la divulgation et/ou la communication d'informations relatives à une personne (génotype) etc. Si la déclaration associe science et société dans une même formulation elle risque d'alimenter un débat sans fin ce qui nuira à la mise en œuvre de la déclaration.

Nous proposons donc de parler de *primauté de la personne humaine sur le seul intérêt de la science*.

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

This article is ambiguous. It declares on one hand the superiority of mankind over the "rest" of creation; this is the anthropocentric principle which can not be maintained in the light of the contemporary developments. On the other hand the primacy of the human person is useful during sunny times only. In war times, as for example during the second world war, the interest of society to defend itself against criminal aggression prevails and soldiers have to resign to their fate.

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

It is important not to draw too rigid a distinction between the interests of the human person and of society (of which, of course, persons are members); although we recognise that the potential for conflicting interests can sometimes arise.

We therefore agree with the spirit of this article and welcome the qualification “sole”. However, we suggest that this article is ambiguous and could be interpreted as suggesting that protecting an individual even against marginal risk of harm should prevail over important societal interests or advances in science (e.g. sharing patient identifiable data to cancer registries, without patient consent).

We therefore suggest the following re-wording: “*Any decision or practice within the scope of this Declaration must not infringe fundamental human rights or involve the exploitation of the vulnerable*”.

Article 9 - Non-Discrimination and non-Stigmatization

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We suggest clarifying that the nature of the discrimination at issue is *unjust* discrimination.

Article 10 - Autonomy and Responsibility

ASSOCIATION ASIATIQUE DE BIOÉTHIQUE / ASIAN BIOETHICS ASSOCIATION

The title reads “autonomy and responsibility” however the contents are autonomy and liberty. We would suggest the title be “**autonomy, liberty and responsibility**”, and a second sentence on human responsibility for their moral choices be added. In Asian traditions the responsibility is very important.

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We are unclear about the relevance of ‘responsibility’ in the title section to the rest of the article. We also suggest changing the words ‘without prejudice’ with ‘that do not prejudice’ for clarity’s sake.

Article 11 - [Informed] Consent

ASSOCIATION MÉDICALE CANADIENNE / CANADIAN MEDICAL ASSOCIATION

Since words in brackets may be adopted or revised, Article 11 may not be restricted to informed consent. One concern is that legitimacy of inferred consent in emergency situations is not recognized. We believe that, since the Declaration is a statement of the universal norms of bioethics, then this norm should be identified and included.

FÉDÉRATION MONDIALE DES TRAVAILLEURS SCIENTIFIQUES (FMTS) / WORLD FEDERATION OF SCIENTIFIC WORKERS (WFSW)

« b) ...l'intérêt supérieur de la personne concernée, **et après avoir sollicité son assentiment** ».

INCLUSION INTERNATIONAL

Article 11 (Informed Consent) does however raise the issue of appropriate use and safeguards in the area of supported decision-making. On this issue we would urge the Committee to consider additional wording to avoid in appropriate use of substitute decision-making and legal guardianship. The Montreal Declaration on Intellectual Disability adopted by PAHO (October 2004) outlines a proposed approach to these issues.

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“a) Deberá obtenerse el consentimiento previo, libre, informado y expreso **escrito o debidamente contrastado sin que medien intereses de otros** de las personas interesadas para cualquier investigación médica o científica, y para cualquier tratamiento o diagnóstico. Ese consentimiento se podrá revocar **por la persona que lo otorgó** en cualquier momento **si con ello no se pone su vida en peligro**.”

b) Si con arreglo a una legislación nacional conforme al derecho internacional relativo a los derechos humanos, una persona careciese de capacidad **cognitiva plena o parcial** para dar su consentimiento, éste [una autorización] tendrá que obtenerse de su representante legal **o del ministerio fiscal**, teniendo presente el interés superior de la persona de que se trate. **En el caso que la limitación cognitiva de la persona lo permita, esta será quien consienta sobre cuestiones concretas que le atañen.**”

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We have concerns that this article fails to acknowledge that there may be acceptable exceptions to the requirements for express consent to all medical or scientific research. In the UK, for example, under the Human Tissue Act (2004) the secondary use of anonymised tissue samples will not require (legal) consent, although other safeguards will be in place to ensure that participants’ interests are protected. UK law also allows for cases where patient identifiable data can be disclosed to third parties (e.g. for epidemiological research) without consent, on the advice of a statutory body (the Patient Information Advisory Group).

With regards withdrawal, we would distinguish between withdrawal from a procedure involving a physical intervention (such as taking medication or donating blood) and withdrawal of participation where there is no physical intervention (e.g. using data or secondary use of stored tissue samples). In the former case, we would classify this type of withdrawal as ‘withholding consent’ and in the latter, as ‘withdrawing from participation’.

We maintain that all competent adults have an unqualified right to withhold consent to a procedure involving a physical intervention. In the case of withdrawing from participation, however, the Declaration should recognise that, it will sometimes only be possible to offer a limited range of options for withdrawal, a point which has been recognized in UNESCO’s ‘International Declaration on Human Genetic Data’.

We suggest that the Declaration should distinguish between these two categories and, in the case of research involving secondary use of tissue samples or data, state that the options for withdrawal (which may range from full withdrawal to withdrawal being impossible) should be clearly explained to donors at the consent stage.

We would therefore reword the article as follows: “*a) All competent persons have the right to give or withhold consent to medical or scientific research, treatment or diagnosis. This consent should be voluntary and informed. In the context of participation which does not involve a physical intervention but where ongoing use of data or stored tissue samples is required for research, the options for such withdrawal should be canvassed at the consent stage. Any exceptions to these requirements must be in line with domestic legislation and international human rights law*”.

Article 12 – Privacy and Confidentiality.

CENTER FOR COGNITIVE LIBERTY & ETHICS (CCLE)

“Any decision or practice within the scope of this Declaration shall be made or carried out with **full** respect for the privacy of the persons concerned and the confidentiality of their personal **biological and neurological** information. **Such information shall not be used or disclosed for purposes that violate individual privacy, autonomy and choice. Nor can such information...**”

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“... Esa información no se podrá utilizar o revelar para fines distintos de los previstos para recogerla, salvo que la persona interesada dé su consentimiento [con los requisitos establecidos los apartados a) –primer párrafo- y b) del artículo 11], o cuando se trate de casos restrictivamente previstos por la legislación nacional de conformidad con el derecho internacional relativo a los derechos humanos. **Se deberá cautelar que esa información consentida no afecte arbitraria y negativamente a terceras personas.**”

Article 13 - Sharing of Benefits

ASSOCIATION ASIATIQUE DE BIOÉTHIQUE / ASIAN BIOETHICS ASSOCIATION

This is an important article. In the principle of biocentric bioethics we would also suggest a new item, before the existing vii) to read: *“vii) sharing benefits of research for the welfare of non-human species who contributed to the research;”*. The article could be made more focused and proactive stating that measures will be taken to promote the transfer of technologies and the building of capacity in developing countries.

CONSEIL DES ORGANISATIONS INTERNATIONALES DES SCIENCES MÉDICALES / COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES (CIOMS)

This article is particularly important and the terms used should be clear and comprehensive. CIOMS proposes the term **“medical products”** instead of “drugs”. Medical products include medicines, pharmaceuticals, cell or organ transplants, medical devices, new methods of administration of therapeutic products (such as slow infusions into a vein), technical devices used in orthopaedic surgery, vaccines and other preventive products, etc. “Medical products” has been used in WHO resolutions and documents as a comprehensive term in similar contexts.

FÉDÉRATION INTERNATIONALE DES UNIVERSITÉS CATHOLIQUES (FIUC) / INTERNATIONAL FEDERATION OF CATHOLIC UNIVERSITIES

L'article 13 porte sur le partage des bienfaits. Ce principe doit dériver de ceux de la justice, de la solidarité, de l'équité et de la coopération. Nous nous demandons s'il ne serait pas approprié de parler du bien commun et de la destination universelle des biens de la terre qui situeraient peut-être mieux la question de la propriété privée, de la propriété intellectuelle et de la brevetabilité du vivant. L'idéal de justice distributive devrait être vigoureusement affirmé. Il s'agit de rappeler la juste répartition des charges et des avantages de la vie sociale.

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

In principle agreed; however difficult to apply to daily life of (all) societies. In addition, not all results from scientific research can be communicated; they may be too difficult or too dangerous.

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“De conformidad con el derecho internacional y el nacional, los beneficios resultantes de la investigación médica y científica serán **puestos a disposición** y compartidos ...:

- (vi) **participación económica para los sujetos sometidos voluntariamente a una investigación que derive en productos, etc. Comercializados”**.

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We suggest adding the following sentence at the end of the article: *“However, care should be taken to ensure such benefits do not create an undue influence to participate in research and should not damage the local research environment by raising unrealistic expectations that subsequent research will provide similar benefits”*.

PROCEDURAL PRINCIPLES

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

Titulo: ~~Principios~~ **Conductas** en materia de procedimiento

Article 14 - Honesty and Integrity

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

- “(i) aplicarse con independencia y honradez intelectual **y profesional**;
- (ii) respetar la necesidad de integridad **personal** en la **práctica profesional** y en investigación científica o de otro tipo”.

Article 15 - Transparency and Openness

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

- “(ii) determinarse teniendo presentes, en particular, **el respeto a los derechos** y las circunstancias conocidas de las personas interesadas;
- (iii) observar el respeto a la vida privada y la confidencialidad, **tal como se dispone en el Artículo 12**;
- (iv) ponerse a disposición de las personas interesadas y de la sociedad ~~civil~~ para que éstas la examinen **y valoren**; y
- (v) ser objeto **previamente** de un debate informado y pluralista, **y siempre con carácter general en los distintos sectores de la sociedad** incluso en **incluyendo** los media.”

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We suggest deleting i) as it is ambiguous and could be interpreted in such a way as to be incompatible with iii). In addition, we suggest that iv) adequately captures the requirements of i). We also suggest deleting v) as this is already addressed at article 21 and because the media are part of ‘civil society’ (see iv)).

Article 16 - Scientific and Rational Methods

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

- “(i) aplicarse sobre la base de la **completa** y mejor información científica disponible;

...

- (iv) respetar, cuando proceda **siempre**, los procedimientos adecuados de evaluación de riesgos **y posibles consecuencias**.”.

Article 18 - Fair Decision-Making Process

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“... conforme a los procedimientos leales **conforme a conocimientos científicos contrastados y a conductas responsables y leales**”.

PROCEDURES

Article 19 - Risk Assessment

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

Important and in principle agreed. However, it is evident that assessments concern short-term damage only and specific threats emanating directly from projects; it is very difficult to assess side effects in other fields. Let’s take the stem-cell discussion; let’s assume that this research is successful, and that the life of some people will be alleviated. The procedures are very expensive, and can not be used for every sick person. Omissions will provoke trouble within societies and between cultures.

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Cuando haya datos científicos que hagan temer un perjuicio grave o irreversible para la salud pública, el bienestar de los seres humanos, **las generaciones futuras o la especie humana** o el medio ambiente [biosfera] **para la biosfera**, deberán adoptarse medidas **precautorias** provisionales, adecuadas y proporcionadas, a su debido tiempo. Esas medidas deberán basarse en los **completos** y mejores conocimientos científicos disponibles y aplicarse de conformidad con los principios enunciados **de conformidad con lo establecido** en la presente Declaración, respetando los derechos humanos y las libertades fundamentales.”

Article 20 - Ethics Committees

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Se deberán crear, promover y apoyar, al nivel que corresponda, comités de **Bioética** independientes, pluridisciplinarios y pluralistas con miras a:

- (i) evaluar los problemas éticos, jurídicos y sociales relacionados con los proyectos de investigación científica y la **aplicación** y evolución de la tecnología; y...”

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

As regards ethics committees’ responsibility to assess the legal issues related to research projects (20 i)), we would point out that in the UK, NHS Ethics committees are not constituted to give legal advice, although they can raise legal issues. It is the responsibility of researchers to explore these legal issues further. We consider this entirely appropriate.

As regards 20 ii), ethics committees in the UK do not generally issue general guidelines or recommendations and there are no plans for a National Ethics Committee. However, there are a number of regulatory or advisory bodies (both statutory and independent) in the UK, such as the Human Fertilisation and Embryology Authority (HFEA); the Human Genetics Commission (HGC); the General Medical Council (GMC) and the Nuffield Council on Bioethics. These organisations regularly consider issues in bioethics and issue specialist guidance, licensing conditions, advice to professionals or government bodies, as appropriate to their remit. We see no reason why these functions need to be assumed by ethics committees rather than other bodies and therefore recommend broadening 20 ii) to include ‘other appropriate bodies’ as well as ethics committees.

Article 21 - Ensuring Public Debate

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“Los Estados velarán por que los ciudadanos tengan la posibilidad de mantener un debate público **continuo**, informado y pluralista, **utilizando el lenguaje accesible y clarificador adecuado a cada caso** garantizando no sólo...”

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We recommend replacing the words ‘Ensuring’ (public debate) with ‘Encouraging’, in the title. We also suggest replacing ‘ensuring the participation of’ (in the article) with ‘and to encourage participation by ‘.

Article 22- Transnational Practices

CENTER FOR COGNITIVE LIBERTY & ETHICS (CCLE)

“International research **and commerce** should be subject to ethical review in the country providing financial support for the activity as well as in the country where the research **and commerce** is to be carried out. This review should be based on the principles set out in this Declaration and on the ethical and legal standards adopted by the States concerned.”

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“La investigación internacional deberá ser objeto de un examen **bioético** en el país que presta apoyo a la actividad, así como en el país en el que tenga que realizarse la investigación. Este examen deberá basarse en los principios enunciados en la presente Declaración y en las normas éticas y jurídicas y **en las orientaciones bioéticas y las normas jurídicas** adoptadas por los Estados interesados.”

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We support the requirement for dual ethics review (in the host and sponsoring country) where those involved or participating in the research come from both or all the countries concerned. However, the Wellcome Trust’s position is that there is no requirement to carry out independent ethics review in the funding country when no individuals or institutions from that country are involved in the research, nor are intended to be the primary beneficiaries of such research. Indeed, the Trust would consider this to be inappropriate and could potentially conflict with article 5 (Respect for Cultural Diversity and Pluralism). In such situations, the Trust would maintain that review in the host country (countries) suffices; although the Trust (and other UK funders) would be unlikely to fund research in other countries that it judged to be unethical or illegal were it to be undertaken in the UK. In cases where the host country does not have an ethics committee, an alternative source of review, such as an appropriate inter-governmental organisation, should be sought.

PROMOTION AND IMPLEMENTATION**Article 23 - Bioethics education, training and information****SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS**

- “a) Estas medidas deberán apuntar a públicos específicos, en particular los investigadores y los miembros de los comités de **bioética**, o dirigirse al público en general.
b) Los Estados deberán alentar a las organizaciones intergubernamentales, internacionales y regionales, así como a las organizaciones no gubernamentales, internacionales, regionales y nacionales, a que **la fomenten y participen** en esta tarea.”

OFFICE INTERNATIONAL DE L’ENSEIGNEMENT CATHOLIQUE (OIEC) / CATHOLIC INTERNATIONAL EDUCATION OFFICE

« a) Afin de promouvoir (...) les Etats **devront favoriser** (...) en particulier les chercheurs, les membres des comités d’éthique, **les jeunes, les enseignants et le grand public** ».

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

- a) Important; agreed. In addition, efforts should be taken to enforce ethical behaviour of all kind of media (internet, computer games, television, printed media etc.)
b) It is a question how many organizations should participate in a given discussion. Overload may ruin a discussion as well as a decision.

THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC), THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST

We suggest changing ‘all forms’ (of bioethics training) with ‘**appropriate forms**’.

Article 24 - Solidarity and International Cooperation**CONSEIL INTERNATIONAL DES FEMMES / INTERNATIONAL COUNCIL OF WOMEN (ICW)**

Article 24 is in line with Article 3 of the Resolution adopted by the General Assembly of the ICW in 2000 that takes into account the needs of developing countries and by which the ICW urges “to ensure that within the framework of international cooperation, developing countries should engage in and participate in research into human biology and genetics, taking into account their own specific problems”.

**FÉDÉRATION MONDIALE DES TRAVAILLEURS SCIENTIFIQUES (FMTS) / WORLD
FEDERATION OF SCIENTIFIC WORKERS (WFSW)**

Alinéa b) : L'idée contenue dans la dernière partie de la phrase, présentement placée entre crochets, est essentielle pour parvenir aux objectifs de la Déclaration. Nous souhaitons donc son inclusion sans les crochets.

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“b) Los Estados deberán fomentar la difusión internacional de la información científica y **tecnológica** ...

c) En el contexto de la cooperación internacional, los Estados deberán promover la cooperación científica, **tecnológica** y cultural, ...”.

SIDA INFORMATION SUISSE / AIDS INFORMATION SWITZERLAND

Article 24 b): Very idealistic and eventually dangerous. Some scientific knowledge may not proliferate (chemical-, physical- and bio-weapons); such (technological) knowledge may and will be misused by groups or states, also in developing countries.

**OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) /
CATHOLIC INTERNATIONAL EDUCATION OFFICE**

« a) Les Etats **devront** (...) et ceux dont les ressources sont les plus limitées **voire inexistantes**

b) Les Etats **devront** (...) et **ne s'épargner** aucun effort (...) et le partage, **éventuellement la vulgarisation** des connaissances...

c) Les Etats **devront...** »

**THE HUMAN GENETICS COMMISSION (HGC), THE MEDICAL RESEARCH COUNCIL (MRC),
THE ROYAL COLLEGE OF GENERAL PRACTITIONERS (RCGP) AND THE WELLCOME TRUST**

We suggest replacing the words 'namely throughout the creation of research' with '**by supporting the development of**'.

Article 25 - Role of States

**OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) /
CATHOLIC INTERNATIONAL EDUCATION OFFICE**

« Les Etats **devront** prendre toutes les mesures appropriées, législatives, administratives, **financières** et autres (...). Ces mesures **devront** être soutenues... »

**Article 26- Roles of the International Bioethics Committee (IBC) and the
Intergovernmental Bioethics Committee (IGBC)**

**OFFICE INTERNATIONAL DE L'ENSEIGNEMENT CATHOLIQUE (OIEC) /
CATHOLIC INTERNATIONAL EDUCATION OFFICE**

« a) Le Comité international de bioéthique (...) qui y sont énoncés. Les deux comités **devront** être responsables (...). Il **devra** leur incomber(...). Ils **devront** formuler, suivant les procédures statutaires... ».

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“a) El Comité Internacional de Bioética (CIB) y el Comité Intergubernamental de Bioética (CIGB) contribuirán a la aplicación de la presente Declaración y a la difusión de los principios enunciados en ella **contribuirán a la difusión y aplicación de los contenidos de la presente Declaración...**

b) Los Estados comunicarán **han de presentar** cada dos años sus informes al Comité Internacional de Bioética y, una vez examinados, éste emitirá su dictamen de conformidad con los procedimientos reglamentarios de la UNESCO. Tras haber examinado el dictamen del CIB y los informes comunicados **presentados** por los Estados...”.

Article 27 - Follow-up action by UNESCO

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

- “a) La UNESCO deberá tomar las medidas adecuadas para el seguimiento de la presente Declaración, de manera que se propicien **la buena praxis** y el progreso de las ciencias de la vida y sus aplicaciones gracias a las tecnologías **y sus aplicaciones tecnológicas**, ~~basándose~~ **basados inequívocamente** en el respeto de la dignidad humana y en el ejercicio y observancia de los derechos humanos y las libertades fundamentales.
- b) La UNESCO deberá reiterar su voluntad de tratar todos los aspectos de la biosfera y si es necesario elaborará orientaciones e instrumentos internacionales, según proceda, sobre los principios éticos relacionados **sobre las conductas bioéticas relacionadas con la naturaleza** el medio ambiente y **la biodiversidad** otros organismos vivos.
- c) Cinco años después de su adopción [~~y periódicamente en lo sucesivo~~] **y posteriormente con la periodicidad que el desarrollo de los conocimientos científicos y las aplicaciones tecnológicas lo demanden** la UNESCO adoptará las medidas adecuadas para examinar la presente Declaración a la luz del progreso científico y tecnológico y, cuando sea necesario, la revisará con arreglo a sus procedimientos reglamentarios.
- d) Por lo que respecta a los ~~principios enunciados en~~ **contenidos de** la presente Declaración, podrían desarrollarse mediante instrumentos internacionales adoptados por la Conferencia General de la UNESCO, de conformidad con los procedimientos reglamentarios de la Organización.”

Article 28 - Interpretation

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“~~Los principios enunciados en~~ **Las conductas bioéticas contenidas en** la presente Declaración son interdependientes por lo que respecta a su interpretación y ~~aplicación~~ **puesta en práctica**, y cada **una** principio debe interpretarse en función de los demás.”

Article 29 - Restrictions

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“No se impondrán restricciones a ~~los principios enunciados~~ **lo establecido** en la presente Declaración, salvo las que establezca la legislación [y sean necesarias en una sociedad democrática] por motivos de seguridad pública o para prevenir delitos, proteger la salud pública y salvaguardar los derechos y libertades de los demás **y la especificidad humana.**”

Article 30 - Denial of acts contrary to human rights, fundamental freedoms and human dignity

CENTER FOR COGNITIVE LIBERTY & ETHICS (CCLE)

“Nothing in this Declaration may be interpreted as implying for any States, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms, **including freedom of thought** and human dignity, **with particular reference to** the principles set out in this Declaration.”

SOCIÉTÉ INTERNATIONALE DE BIOÉTHIQUE (SIBI) / INTERNATIONAL SOCIETY OF BIOETHICS

“.....en contra de los derechos humanos, las libertades fundamentales y la dignidad humana, y en particular en contra de ~~los principios enunciados en~~ **en contra de las conductas bioéticas de** la presente Declaración.”

Partie / Part IV

COMITES NATIONAUX DE BIOÉTHIQUE (ou instances assimilées) / NATIONAL BIOETHICS COMMITTEE (or similar bodies)

- *Comité consultatif de bioéthique (Belgique) /
Bioethics Consultative Committee (Belgium)*
- *Comité national de bioéthique (Israël) /
National Bioethics Committee (Israel)*
- *Comité national de bioéthique (République démocratique du Congo) /
National Bioethics Committee (Democratic Republic of Congo)*
- *Comité de bioéthique slovaque (Slovaquie) /
The Slovak Bioethics Committee (Slovakia)*
- *Comité national d'éthique médicale (Tunisie) /
National Committee of Medical Ethics (Tunisie)*
- *Comité national norvégien pour l'éthique de la recherche médicale (Norvège) /
Norwegian National Committee for Medical Research Ethics (Norway)*
- *Commission nationale de bioéthique (Mexique) /
National Commission of Bioethics (Mexico)*
- *Commission nationale de bioéthique grecque (Grèce) /
Hellenic National Bioethics Conseil Commission (Greece)*
- *Comité d'éthique danois (Danemark) /
Danish Council of Ethics (Denmark)*
- *Conseil de la recherche en matière de santé (Nouvelle Zélande) /
Health Research Council (New Zealand)*
- *Conseil national d'éthique des sciences de la vie (Portugal) /
National Council of Ethics for the Life Sciences (Portugal)*
- *Scottish Council on Human Bioethics*
- *The Nuffield Council on Bioethics (Royaume Uni / United Kingdom)*

GENERAL COMMENTS

COMMISSION NATIONALE DE BIOÉTHIQUE (MEXIQUE) / NATIONAL COMMISSION OF BIOETHICS (MEXICO) (DRAFT #7 REV.)

Se recomienda utilizar la nomenclatura de “principio” sin hablar de fundamentales y de derivados y de procedimientos. De hecho, se sugiere hablar por un lado, solamente de principios y en todo caso, jerarquizarlos y ordenarlos de acuerdo con un orden de lo general a lo particular, o algún parámetro filosófico; y las cuestiones de procedimiento, abordarlas como tal, sin el prefijo “principios”; si se considera que algunos de los principios de procedimiento es un principio como tal, entonces incluirlo en esa sección. Se sugiere, además, enumerar cada principio por separado, ya que a pesar de la relación que existe entre muchos de ellos, no son lo mismo y merecen una mención específica. Por otro lado, se repiten el principio de Autonomía en dos lugares diferentes, uno vinculado a consentimiento informado y el otro a responsabilidad. Además, al incluir en el título, dos o tres temas aparentemente conectados y después desarrollar un texto común, en muchos casos la alusión que se hace a uno o a varios tópicos se diluye o está ausente. Finalmente, no son claros los criterios para agruparlos; algunos parecerían no estar en las mismas categorías o rubros o no estar tan estrechamente relacionados como para figurar juntos.

No cabe duda de que la iniciativa de UNESCO, sobre una Declaración sobre Normas Universales de Bioética, es necesaria, interesante y de potencial utilidad para los Estados miembro. Es un enorme reto en pos de lograr acuerdos mínimos entre países diversos y heterogéneos cada uno a su interior, sobre temas sensibles y complejos sobre los que existen una diversidad de aproximaciones y perspectivas. El gran mérito que tiene, es que de lograrse, se contaría con un documento que reflejaría los acuerdos a los que todos, a pesar de las diferencias existentes, pueden suscribir; lo que equivaldría a elaborar un documento de una ética de mínimos, que establecería el substrato básico sobre el que después se construyen las normas éticas y legislaciones nacionales. En aras de alcanzar estos consensos, en ocasiones, los documentos internacionales resultan de un carácter muy general. Esta generalidad, tiene la ventaja de no forzar ningún término con el que alguien pueda sentirse agraviado y por lo tanto no sumarse y deja la posibilidad para que cada país, de acuerdo con su idiosincrasia y legislaciones propias, interprete de manera particular el contenido general de las Guías Universales, lo cual es una ventaja.

La desventaja de la generalidad, estriba, principalmente, en que, en ocasiones, el enunciado de los principios que establecen puede resultar abstracto, y su interpretación prestarse a enormes variaciones en el momento de su traducción e instrumentación, tanto a nivel nacional como institucional. Este surge al discutir un documento de carácter general, que prefiere evitar abordar las especificidades, pero que a su vez se declara preocupado por las condiciones de los países en desarrollo y por el acceso a la tecnología. Por ejemplo la pobreza, la marginación y el escaso acceso a los satisfactores de las necesidades básicas, por la mayoría de los habitantes de los países en desarrollo, son una realidad que atañe alrededor de las dos terceras partes de la población general. Cabe cuestionar el trato periférico que se hace de estos temas en la Declaración, pues a pesar de ser un documento general, la dimensión del problema, aún cuando no es una realidad en todos los países, plantea la duda de donde marcar la frontera entre lo general y lo particular; sobre todo, cuando se trata de un documento que pretende establecer los lineamientos generales de razonamiento bioético, que sea adoptado y represente a todos los Estados miembro; y, finalmente, al recordar que la bioética como disciplina surge en un contexto de francas reivindicaciones sociales .

Es así que parecería importante hacer más explícito en el articulado del documento, el carácter democratizador y reivindicador de las injusticias y su preocupación por los problemas persistentes (pobreza y marginación), sobre todo en los países en desarrollo (a los cuales menciona como foco especial de atención), pero también entre algunos grupos poblacionales que habitan en países desarrollados. Esto es importante para que no se diluya en un documento que pretende servir de marco universal de bioética, uno de sus objetivos originales y que se acapare su atención enfocándola a la resolución de los problemas emergentes, que serían en todo caso, los vinculados con los desarrollos tecnológicos. Sobre todo, porque muchos de los problemas éticos que plantean los desarrollos tecnológicos, están íntimamente vinculados con problemas de falta de acceso y de injusta distribución, de manera que la división entre los problemas emergentes y los persistentes, resulta no solamente arbitraria y teórica, sino poco operativa.

En cuanto a la definición de Bioética: contiene una definición operativa, no conceptual, que es muy útil para la comprensión del alcance y limitaciones del documento, y deja claro a qué se refiere. Sin embargo, se sugiere revisar todo el texto a la luz de ésta definición, que se agregó después, dado que la Declaración parece que en algunos puntos pareciera sólo referirse a lo médico y en otros parece tener una perspectiva más amplia. Por otro lado, si bien la definición de bioética parece adecuada, la de “bioethical” issues, además de ser repetitiva, se queda muy corta en los temas que comprende, sobre todo cuando que se han expresado ya muchas veces a favor de que la bioética abarque temáticas más complejas. Consideramos, además, que eliminar del inciso ii del Artículo 2, el tema del acceso y la disponibilidad, resulta poco afortunado, a pesar de que probablemente la intención haya sido abrir el espectro del ámbito de injerencia del documento; ambas cosas no son excluyentes.

Resulta acertado haber eliminado del clausulado que se diga que cualquier decisión que se tome “within the scope” de la Declaración. Es un acierto que vale la pena resaltar, de la propuesta de UNESCO, de ubicar a los derechos humanos como objetivos centrales a defender y promover.

Falta un enfoque de salud pública y de comunidad. Las Guías propuestas, en su versión actual, no contemplan explícitamente ni abordan suficientemente los dilemas éticos y las recomendaciones pertinentes para los casos de las tensiones que se generan en el ámbito de la salud pública; del conflicto que plantea el bien común contra el bien individual, como es el caso de las epidemias, vacunas, o con las dificultades de un Estado para tomar decisiones en cuanto a la asignación de recursos tanto para la atención a la salud básica, la investigación como para el uso de recursos extraordinarios específicamente dedicados para combatir determinadas epidemias, como es el caso actualmente del sida y los fondos que la OMS destinará a los países. Respecto de este tema, se hace una vaga y e insuficiente alusión en el art. 29 al decir que los temas de salud pública privan por sobre los intereses del individuo. Por otro lado, los individuos se organizan en comunidades, las cuales requieren de una aproximación distinta del concepto del ejercicio de las libertades y de los procesos de toma de decisión; y que conlleva sin duda a enormes dificultades porque la definición de comunidad y de sus representantes, son temas lejos de estar resueltos. Sin embargo, el tema de la ética y la comunidad no puede quedar excluido. Mencionar en los considerandos y en el artículo 2 que aplica a individuos, familias o comunidades, es un avance respecto de las versiones anteriores, pero no resuelve el problema.

Otro de los aspectos que sería recomendable matizar en la actual propuesta, es el hecho de que está demasiado centrada en la Ciencia y tecnología. Cuáles serían algunos de los inconvenientes de ésta situación:

1 Que la bioética no surge únicamente como respuesta a los dilemas que se derivan de la ciencia y la tecnología

2 Que hablar de ciencia y tecnología resulta reduccionista y riesgoso por varias razones: El panorama actual no es solamente muy complejo, está marcado por desafíos que sobrepasan distinciones entre ciencia y no ciencia y diversos tipos de ciencia. Al margen de las decisiones conceptuales sobre las definiciones de la ciencia y la investigación y sobre la contundencia de unas ciencias sobre otras, el peligro que se corre es el de seguir ignorando y excluyendo del mandato de una Declaración Universal de bioética, a los sujetos que no quedan definidos como tales desde los paradigmas de la globalización, y que son, por un lado, aquellos que no tienen acceso alguno a los servicios básicos, a la tecnología y a la investigación, y por otro, quedarían fuera del ámbito de éste documento, quienes participaran en investigación en el campo de la salud mental y la ciencias sociales; no hay que olvidar, que se trata de personas que participan en investigación, que requieren de cuidados éticos y de que las investigaciones en las que participan se ciñan al rigor metodológico correspondiente- Las disciplinas no médicas, requieren de una reflexión similar a la que se propone para las médicas, científicas y tecnológicas.

3. Necesidad de articular mejor la multidisciplinariedad. El objetivo de las guías universales en bioética es que buscan promover el bienestar, el respeto a los derechos humanos y a las libertades básicas, y preservar y promover la dignidad humana; sin embargo, la ciencia y la tecnología no son los únicos factores que aportan a la salud. Tampoco son la ciencia y la tecnología los únicos que aportan al bienestar y a la posibilidad del ejercicio de

los derechos humanos. La solución, y sobre todo la comprensión, de los problemas de salud y a su acceso a los servicios, así como su ejercicio como derecho humano, no están exclusivamente en la ciencia y la tecnología, ni son ellas las únicas formas de generar conocimiento sobre la realidad de las personas. De ahí que el reforzar la multidisciplinariedad, que está contemplada en el documento, adquiere una relevancia mayor.

4. Si se ampliara el espectro de investigación y se fomentara la multidisciplinariedad, no se limitaría a la ciencia y la tecnología y se lograrían avances en la definición de los beneficios. Cabría añadir, que la información no necesariamente es científica ni técnica, sino que también se deriva de la investigación en otros campos. La devolución de la información, producto y posible beneficio de la investigación, debe de ser una herramienta de empoderamiento, de reorganización, detonador de reflexión y promover una nueva forma de vida, que incluye cambio de hábitos, y que la inclusión de expertos en otros campos, puede contribuir al mayor éxito de programas de prevención.

Para resumir, parece inadecuado centrar el documento en la ciencia y la tecnología, dado que el mandato de UNESCO contempla el desarrollo de normas que guíen el desarrollo tecnológico y la transformación social. Parecería haber una interpretación parcial del mandato, ya que la ciencia y la tecnología, ni son la única herramienta de la transformación social (y de ahí la necesidad de reforzar en el documento mismo la multidisciplinariedad) ni son las únicas ni las mejores herramientas de promover y proteger la dignidad humana, otro de los objetivos del documento. Aquí cabría acotar que en diferentes partes la Declaración hace énfasis en hacer accesibles a todos los resultados del desarrollo científico y tecnológico y lograrlo, solo eso, sería un avance impresionante en el bienestar de la Humanidad y contribuiría a la transformación social.

Otra de las sugerencias que vale la pena hacer, es incluir algunas consideraciones sobre la falta de definición o diferenciación que en ocasiones se plantea entre procesos experimentales e investigación y la tenue línea que separa la clínica de la investigación, dado que ésta es otra puerta abierta a posibles violaciones de derechos y de principio éticos básicos como los que se proponen en estas Guías, entre ellos, el consentimiento informado.

Consideramos que es importante que un documento que emite un organismo como UNESCO, se refiera de manera más directa a situaciones como las inequidades en el financiamiento de investigación misma que se hace patente en la ecuación 90/10, que se refiere a que el 90% de los recursos de investigación se dirigen a aliviar las enfermedades que aquejan únicamente al 10% de la población. De hecho, la semana pasada, acaba de concluir el Foro Global de Investigación en Salud en nuestro país, cuya finalidad es fomentar los mecanismos para remontar ésta situación.

Que unas guías universales de bioética, promovieran que desde la investigación misma, no solamente se evite la discriminación y la estigmatización; sino que sean muy claras respecto de que es necesario evitar aprovecharse de estas condiciones para llevarla a cabo; además, no promover acciones ni investigaciones que perpetúen la situación de discriminación, lo cual no aparece de manera explícita en el texto. En ningún momento en el documento se consideran las acciones afirmativas para remontar las inequidades y probablemente valdría la pena explorar ésta posibilidad, desde la investigación.

**COMITÉ NATIONAL D'ÉTHIQUE MÉDICALE (TUNISIE) /
NATIONAL COMMITTEE OF MEDICAL ETHICS (TUNISIE)**

Le projet de texte dans sa version actuelle, adressé aux gouvernements des Etats membres de l'UNESCO comprend notamment des principes répartis selon une distinction judicieuse entre principes fondamentaux, principes dérivés, principes procéduraux et procédures.

Le Comité National d'Éthique Médicale estime que la future Déclaration doit être un texte qui proclame des principes généraux en matière de bioéthique (y compris des procédures). L'important dans cet instrument international est de faire reconnaître l'importance primordiale des valeurs de la bioéthique. Pour les sujets spécifiques, ils devraient donc faire l'objet de textes spécifiques qui prennent aussi en compte les principes énoncés et les rapports déjà publiés par le CIB sur les questions spécifiques.

Si les progrès scientifiques et leurs applications ont considérablement amélioré les conditions de vie de l'humanité, force est de constater l'importance des questions éthiques qu'ils soulèvent. Aussi une coordination à l'échelle internationale sur la définition des principes universels serait-elle absolument nécessaire. Etant la seule organisation internationale du système des Nations- Unies investie d'un mandat éthique., l'UNESCO est donc la plus qualifiée pour l'élaboration d'un instrument contraignant à caractère universel sur la bioéthique servant de référence aux Etats membres pour légiférer à seule fin de protéger la vie et la dignité humaines et les droits fondamentaux de l'homme.

**COMITÉ DE BIOÉTHIQUE SLOVAQUE (SLOVAQUIE) /
THE SLOVAK BIOETHICS COMMITTEE (SLOVAKIA)**

At present time the SBC has had no contributions and modifications in the consultation for the elaboration of the Third Outline of the future declaration.

**COMITÉ NATIONAL NORVÉGIEN POUR L'ÉTHIQUE DE LA RECHERCHE MÉDICALE (NORVÈGE) /
NORWEGIAN NATIONAL COMMITTEE FOR MEDICAL RESEARCH ETHICS (NORWAY)**

Declarations should basically address essential issues related to the fundamental intentions of the declaration in question, and should not include specific procedural prescriptions in practical matters. In our opinion the third draft does not comply with this principle. We are concerned about the detailed nature of some of the proposed articles, which could result in unintended and unwarranted restriction to ethically sound medical research. We once more wish to underline the importance of avoiding the inclusion of detailed regulations in the declaration.

**COMMISSION NATIONALE DE BIOÉTHIQUE GRECQUE (GRÈCE) /
HELLENIC NATIONAL BIOETHICS COMMISSION (GREECE)**

At this stage of the elaboration of the Declaration on Universal Norms on Bioethics (Third Outline) our Commission has no comments to add.

**CONSEIL DE LA RECHERCHE EN MATIÈRE DE SANTÉ (NOUVELLE ZÉLANDE) /
HEALTH RESEARCH COUNCIL (NEW ZEALAND)**

Categorisation of Principles: The HRCEC supports the distinction made by the IBC drafting group between general principles (basic principles that cannot be justified by any other principle), derived principles (principles that can only be justified by one or more fundamental principles), procedural principles and procedures. On the basis of this rationale however, it is the HRCEC's view that the General [Fundamental] Principles should be limited to the following:

- Article 3-Human Dignity, Human Rights and Justice;
- Article 6-Solidarity, Equity and Cooperation; and
- Article 7- Responsibility towards the Biosphere.

The three principles reflect the distinction recognised by the IBC drafting group in its fourth meeting and recorded at paragraph 5. of its Final Report, they are as follows:

- principles directly related to the respect for human dignity;
- principles concerning the relationship between human beings; and,
- principles governing the relationship between human beings and other forms of life and the biosphere.

We consider the following principles, currently categorized as General Principles, should be categorized as Derived Principles:

- Article 4, Beneficence and Non-Maleficence; and
- Article 5, Respect for Cultural Diversity and Pluralism.

The two principles directly relate to the respect for human dignity (para 3.3.1) and can be justified by the General Principle of Human Dignity, Human Rights and Justice in Article 3 (para 3.2.1) (or if Article 5, relates to a group of people, rather than the individual, we are of the view it could be justified by the general principle in Article 7-Solidarity, Equity and

Cooperation, concerning the relationship between human beings). It is our view that the principles are therefore appropriately categorized as Derived Principles, alongside Article 10, Autonomy and Responsibility and Article 11, Informed Consent.

Hierarchy of Principles: We consider that it should be made clear in the future declaration whether there is any hierarchy between the principles. A hierarchy appears to be suggested in Article 5 and Article 8.

Dealing with certain central topics: We consider that the future declaration should be a text that proclaims the general (universal) principles, including procedures, in the fields of bioethics without dealing with certain central specific topics.

NUFFIELD COUNCIL ON BIOETHICS

The current draft Declaration covers a wide range of issues and has the potential to be a useful reference document for policy makers seeking to devise guidance and regulation in the area of bioethics. However several questions with regard to relation the structure and content of the draft Declaration require further clarification. Our principal concern relates to the possible option of addressing ‘specific issues’ in the Declaration, and we would advise against doing so. We also note that several important issues remain unclear in the current draft, especially (a) the relationship between the different Fundamental Principles; (b) the relationship between the norms of the Declaration and the law in individual states; (c) the relation of the concept of ‘human being’ to the concept of the ‘human person’; (d) the relationship between human beings and animals; and (e) the characterisation and role of the concept of ‘informed consent.’ More detail on these points is provided below.

SCOTTISH COUNCIL ON HUMAN BIOETHICS

Ethical principles related to the duties and responsibilities of humankind towards the biosphere should be done in a separate document and not in the proposed Universal Declaration on Bioethics, otherwise it would (1) undermined the primary aims of the Declaration which is to protect human dignity, and (2) threaten the scope and clarity of the text. It would be appropriate to consider the future declaration as a text that proclaims general principles in the field of bioethics, with concrete subjects to be dealt with in other texts, taking into account the stated principles and the reports already produced by IBC on specific issues.

With respect to the different articles of the Declaration, these are often too long with too many bullet points. This considerably undermined the ‘thrust’ of the Declaration while having the unfortunate effect of undermining its ‘poignancy’ and clarity. If too much detail is present in the Declaration it will become difficult to use. Only the most important principles should be considered. In addition, a lot of what is present in the articles such as explanations etc. could be incorporated into the accompanying explanatory report.

TITLE

COMITÉ NATIONAL D’ÉTHIQUE MÉDICALE (TUNISIE) / NATIONAL COMMITTEE OF MEDICAL ETHICS (TUNISIE)

Le projet de texte dans sa troisième ébauche énonce des *principes* et non pas des *normes*. C’est pourquoi, il serait plus juste que l’intitulé de la déclaration soit « Déclaration Universelle sur la bioéthique et les êtres humains ».

COMMISSION NATIONALE DE BIOÉTHIQUE (MEXIQUE) / NATIONAL COMMISSION OF BIOETHICS (MEXICO)

Es confuso llamarle a la vez Declaración y Normas ambas de carácter universal. Consideramos que dado el contenido y objetivos del documento, el nombre más adecuado sería Declaración.

CONSEIL NATIONAL D’ÉTHIQUE DES SCIENCES DE LA VIE (PORTUGAL) / NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES (PORTUGAL)

“Universal Declaration on Bioethics and Human Beings”.

SCOTTISH COUNCIL ON HUMAN BIOETHICS

“Universal Declaration on Human Bioethics”.

PREAMBLECOMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) /
BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)

2^{ème} alinéa, troisième ligne : remplacer « d’orienter » par « **de soutenir** ».

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAËL) /
NATIONAL BIOETHICS COMMITTEE (ISRAËL) (DRAFT #8)

“Aware that human beings are an integral part of the biosphere and that they have responsibilities and duties towards other forms of life **and quality of the environment for the benefit of present and future humanity**”.

NUFFIELD COUNCIL ON BIOETHICS

Paragraph 3, line 4 and 5 (and paragraph 4): As pointed out in our previous submissions, it would be helpful to clarify the way in which the provisions of the Declaration relate to the Conseil de l’Europe / Council of Europe’s 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; and the ‘other international and regional instruments’, which presumably refers to documents such as the WMA’s Declaration of Helsinki. Is the relationship thought to be complementary? Is it intended that the Declaration provides an overarching framework? Answers to these questions would be useful to avoid conflicts which are likely to arise if the provisions of the Declaration contradict the provisions of other guidelines. We note that similar comments appear to have been made at the Fifth Meeting of the IBC Drafting Group and we welcome the decision by the Group ‘to make explicit reference to certain texts drawn up by non-governmental organizations that have acquired a place of primary importance in the field of bioethics within the scientific community’.

Paragraph 7, line 2: ‘...the special needs of developing countries...’ It would be more appropriate to refer to the needs of *people* in developing countries, rather than to the needs of *developing countries*. Furthermore, while there is no question that people in developing countries have ‘special needs’, it may also be useful to acknowledge that living in challenging environments has contributed to the emergence of *special capacities* of people in developing countries. Acknowledging these capacities by rephrasing thus ‘...taking into account the special needs and capacities of people in developing countries..’ appears to be relevant to the discussion of ‘Sharing of benefits’ under *Article 13*. Technology transfer addressed under point (v) *ibid.* should be sensitive to strategies developed by people in developing countries to deal with, for example, malnutrition or ill health.

[USE OF TERMS] (LIMITED TO SCIENTIFIC TERMS)COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) /
NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)

La notion de « dignité humaine » devrait être définie.

COMITÉ NATIONAL D’ÉTHIQUE MÉDICALE (TUNISIE) /
NATIONAL COMMITTEE OF MEDICAL ETHICS (TUNISIE)

La section « *Définitions* » devrait être maintenue en tête de la Déclaration et inclure obligatoirement la définition de la « Bioéthique ».

GENERAL PROVISIONS

Article 1 - Scope

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) /
NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

- “(i) apply to ~~human beings~~ individuals, families, groups or communities [and humankind as a whole], while recognizing that human beings have responsibilities and duties ~~and responsibilities~~ towards other forms of **life and quality of the environment in the biosphere for the benefit of present and future humanity**; ~~and~~
- (ii) apply to *bioethical* issues **raised by scientific and technological developments** ~~and their applications, as well as their availability and access;...~~”.

CONSEIL NATIONAL D'ÉTHIQUE DES SCIENCES DE LA VIE (PORTUGAL) /
NATIONAL COUNCIL OF ETHICS FOR THE LIFE SCIENCES (PORTUGAL)

The large scope of the Declaration is welcomed.

COMITÉ NATIONAL D'ÉTHIQUE MÉDICALE (TUNISIE) /
NATIONAL COMMITTEE OF MEDICAL ETHICS (TUNISIE)

Le Comité National d'Éthique Médicale est tout à fait d'accord avec le CIB qui a préféré développer un texte ayant trait essentiellement à l'être humain, tout en soulignant les devoirs et responsabilités que l'homme a envers la biosphère et en affirmant la nécessité de traiter de tous les aspects de la biosphère à travers l'élaboration de principes directeurs et d'instruments internationaux, selon qu'il conviendra, concernant les principes éthiques applicables à l'environnement et la faune animale.

Article 2 - Aims

COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) /
BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)

Deuxième tiret : « ...des libertés fondamentales dans chaque prise de décisions en matière de bioéthique, conformément aux droits de l'homme » .

Quatrième tiret : première ligne: biffer « grands ».

Sixième tiret : « de promouvoir l'échange, la mise en commun et la plus large circulation..., ainsi que des bienfaits qui en découlent et ce en particulier... ».

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) /
NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“(ii) to ~~ensure~~ **promote** the respect for human dignity and the protection [**and promotion**] of human rights and fundamental freedoms in [the sphere of] bioethical decision making [*alternative formulation: in decision making in the field of bioethics*], in accordance with **international** human rights law;”.

“iii)” should be placed as number VII:

VII) to promote respect for biodiversity

VIII) to safeguard and promote interests of present and future generations

Suggested additions:

- “- to promote the values of responsibilities upon individuals and society
- to promote the importance of solidarity between individuals and groups”.

NUFFIELD COUNCIL ON BIOETHICS

“...ethical principles that respect human dignity and protect human rights...” We note that *moral agents* are capable of respecting human dignity and respecting human rights, but ‘ethical principles’ are not capable of acting in such, or any other way, and the Article should be redrafted accordingly.

GENERAL [FUNDAMENTAL] PRINCIPLES

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAËL) / NATIONAL BIOETHICS COMMITTEE (ISRAËL) (DRAFT #8)

Title: “General principles”.

COMITÉ NATIONAL D'ÉTHIQUE MÉDICALE (TUNISIE) / NATIONAL COMMITTEE OF MEDICAL ETHICS (TUNISIE)

S'agissant des principes généraux, le CNEM estime que la terminologie la mieux adaptée (ou la plus adéquate) serait « *Principes fondamentaux* » et que le premier principe fondamental est « *le respect absolu de la vie* ». Ce principe devrait figurer à l'article 3 du projet de texte (art. 3 – *Respect de la vie, dignité humaine, droits de l'homme et justice*).

Article 3 - Human Dignity, Human Rights and Justice

COMMISSION NATIONALE DE BIOÉTHIQUE (MEXIQUE) / NATIONAL COMMISSION OF BIOETHICS (MEXICO) (DRAFT #7 REV.)

En el artículo 3 (*Article 3 – Human Dignity, Human Rights and Justice*), en el capítulo de principios generales, se propone que “las prácticas y decisiones que se tomen en el ámbito de las Normas Universales, se deberán regir por el principio universal de justicia”. Sin demeritar la importancia de que la justicia aparezca como uno de los principios rectores, cabe enfatizar la redacción del artículo que se refiere a éste principio como “universal” de manera tal que parecería que existe una lectura unívoca y plenamente aceptada del mismo. Sin embargo, este principio, ha sido motivo de muchos desarrollos conceptuales, cuya descripción o análisis rebasan los límites de la presente exposición. Baste con decir que tiene, en una de sus acepciones, al menos cinco formas de ser comprendido, y las podemos encontrar expresadas en otro documento de referencia internacional en el campo de la investigación, como es el Informe Belmont.

COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) / NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)

Souhaite que les termes « personne humaine » soient remplacés par « tout être humain », compte tenu des acceptations ambiguës que renferme parfois la notion de personne.

NUFFIELD COUNCIL ON BIOETHICS

- ‘...inherent dignity of the human person,...’ It is noteworthy that the Article does not consider the inherent dignity of all human *beings*, but of the human *person*. *Article 1 – Scope*, by contrast, states that the *Declaration* is intended to ‘...apply to human *beings*,...[emphasis added]’. It would be helpful to clarify the relationship between the (scientific) concept of the human being and the (metaphysical, cultural or legal) concept of the human person. This point is particularly important because the application of the concept of human dignity to early developmental stages of human beings is not straightforward. We also observe that the *Universal Declaration of Human Rights*, referred to in recital 2 on page 1 of the *Declaration* states that ‘All human beings are *born* free and equal in dignity and rights’ (emphasis added).

- ‘...the universal principle of justice...’ It would be useful to clarify which concept of justice is being referred to: distributive? procedural? Is the intention behind this Article to state that human dignity, human rights and fundamental freedoms *encapsulate* the principle of justice? If so, it would be useful to rephrase the text accordingly.

- It would also be helpful to clarify the relationship between the ‘universal principles’ (referred to here in ‘...the universal principle of justice...’) and the Fundamental or General Principles, which are set out in Articles 3-7: Are some Fundamental or General Principles universal, whereas others are not? It is not clear why the category of ‘universal’ principles is introduced here (see also the two title-options for the *Declaration*, and Article 5).

Article 4 - Beneficence and Non-Maleficence

COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) / NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)

Remplacer l'expression « réduire au minimum » par « **réduire le plus possible** » ou « **minimiser** ».

COMITÉ NATIONAL D'ÉTHIQUE MÉDICALE (TUNISIE) / NATIONAL COMMITTEE OF MEDICAL ETHICS (TUNISIE)

Quant à l'intitulé de l'art. 4, il est proposé *Efficacité et innocuité*.

« Toute décision ou pratique relevant de la présente Déclaration doit s'efforcer **d'optimiser** les effets bénéfiques à en attendre et d'en réduire au minimum les effets nocifs éventuels pour les personnes concernées ».

SCOTTISH COUNCIL ON HUMAN BIOETHICS

“Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the **best interests of a person while minimising** ~~benefits and minimize~~ the possible harms of such a decision or practice [to the persons concerned].”

Note: Best interests is defined as the highest level of well-being that is achievable for a specific person. Best interests cover medical benefit and the respect for the wishes and beliefs of the patient including his or her spiritual and religious beliefs.

Article 5 - Respect for Cultural Diversity and Pluralism

COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) / BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)

Dernière phrase : « Toutefois, la diversité des valeurs et des traditions ne doit... ».

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“Any decision or practice ~~within the scope of this Declaration~~ shall take into account [*or: **strive to respect the diversity of***] the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious **and spiritual** beliefs ~~and like considerations~~ **that make up our societies**. However, cultural diversity [such considerations] shall not be invoked to infringe upon the ~~universal~~ principles set out in this Declaration, nor to limit their scope. **These general principles should be interpreted in a way that is compatible with cultural diversity.**”

COMMISSION NATIONALE DE BIOÉTHIQUE (MEXIQUE) / NATIONAL COMMISSION OF BIOETHICS (MEXICO) (DRAFT #7 REV.)

La Declaración de Guías Universales plantea, y esto es sin duda una de las virtudes del documento, respetar la individualidad pero a la vez la diversidad cultural, en el marco del ejercicio de los derechos humanos y las libertades elementales; sin embargo, los derechos humanos son francamente violados en muchas culturas y comunidades como parte de su identidad. Tanto es así, que el documento mismo contempla la aclaración que la diversidad no debe de servir de pretexto para violar los derechos humanos. Consideramos que éste es un campo de trabajo multidisciplinario, que debe incluir a las áreas sociales y a las Humanidades dentro del debate y no sólo a la biomedicina. El conocer e interpretar al otro en su pensamiento y su cultura, es una tarea que será sin duda más exitosa si se incorpora la perspectiva social y humanista. El mismo criterio vale para los artículos contenidos en la sección de principios derivados y la evaluación del riesgo. (Art 16 iv).

COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) / NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)

Nouvelle formulation : « [...] *Toutefois ces considérations ne doivent pas être invoquées pour porter atteinte aux principes de respect de la dignité humaine tels qu'énoncés dans la présente Déclaration.* »

NUFFIELD COUNCIL ON BIOETHICS

‘...cultural diversity shall not be invoked to infringe upon the universal principles set out in this *Declaration*...’ In this Article it appears that the term ‘universal principles’ is synonymous with the terms ‘General’ or ‘Fundamental Principles’ (Articles 3-7). If so, and if the term ‘universal principles’ is to be retained, in order to avoid a possible circularity, ‘other’ should probably be added between ‘the’ and ‘universal’, since cultural diversity itself is introduced as a universal principle.

Furthermore, the qualification of this particular principle raises the question of the hierarchical relationship between the various principles, since it appears that ‘cultural diversity’ is of a lower rank than the other principles. This ranking appears to be in contrast with the outcome of the discussion of the IBC Drafting Group at the Fourth meeting.³ If qualifications concerning the standing of particular Fundamental Principles are introduced it would seem consistent to clarify the ranking of other principles too. In particular it would be relevant to clarify the relationship between Articles 3, 4 and 8. Article 8 does not really seem to be a derived principle, in the sense that it would be a more concrete and particular articulation of a fundamental principle. Rather, it appears to establish priority of Article 3 over Article 4, in those cases where Article 4 could be used to argue for a maximisation of benefits to society at the expense of individual persons. However, if this is the function of Article 8 it appears to be either a Fundamental Principle itself, or, otherwise it could be used as a basis to illuminate the question of the hierarchical order of the fundamental principles. It does not appear that Article 28 (*Interpretation*) offers much help in this respect.

Article 6 - Solidarity, Equity and Cooperation

COMMISSION NATIONALE DE BIOÉTHIQUE (MEXIQUE) / NATIONAL COMMISSION OF BIOETHICS (MEXICO) (DRAFT #7 REV.)

Se menciona la equidad como uno de los valores a promover, y si bien son muchas las formas de inequidad y muchos los grupos marginados. A pesar de comprender el carácter general del documento, un ejemplo de inequidad que se antoja preguntar si no debería incluirse, sería la del género (no se habla solo de mujeres; género se refiere a la construcción social del significado de masculino y femenino con base en las diferencias anatómicas y biológicas), en virtud de que constituye un indicador que mejor resume un gran número de inequidades. Corregir las inequidades de género es corregir muchas inequidades. Cuando uno intenta abatir los índices de analfabetismo, no solo ayuda a las mujeres, que además, estamos hablando del 50% de la población del mundo, no de grupos pequeños que son víctimas de exclusiones. De hecho, la conclusión de las últimas conferencias mundiales de población ha sido justamente que un elemento fundamental del desarrollo social y económico de los países, es promover la educación, la salud y el acceso a empleos dignos a las mujeres y a los grupos marginados. Existen, además, antecedentes de otros documentos internacionales en los que se ha incluido el género de manera explícita, en temas afines a la bioética, como la defensa de la biodiversidad, en virtud de que se ha comprobado que de no ser así, las posibilidades de logros son muy escasas.

Article 7 - Responsibility towards the Biosphere

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“Article 7 8 – Responsibility Duties towards the Biosphere

Any decision or practice ~~within the scope of this Declaration~~ shall have due regard for ~~their~~ **its** impact on all forms of life and their interconnection and the special ~~needs-responsibility of human beings~~ **needs-responsibility of human beings** for the protection of biodiversity and the biosphere within which human beings exist.”

SCOTTISH COUNCIL ON HUMAN BIOETHICS

Article 7 should not be included here but in another UNESCO document on the Biosphere. In the context of this Declaration it undermines the concept of human dignity.

DERIVED PRINCIPLES

Article 8 - Primacy of the Human Person

NUFFIELD COUNCIL ON BIOETHICS

In this Article, ‘primacy of the human person’ appears to be introduced with the intention of prohibiting utilitarian ‘sacrifices’ of individuals. We realise that in theological discussions *primacy* is sometimes used in this way. However, commonly, the use of humans as a *mere* means to an end is viewed as morally unacceptable by reference to the (Kantian) philosophical concept of *autonomy*. The concept of primacy, by contrast, appears to be invoked more often when discussing the moral status of human beings and animals. It would be helpful to clarify both concepts, particularly since Article 10 (Autonomy and Responsibility) would benefit from clearer drafting.

If it is intended to address the primacy of human beings over other forms of life, it is not straightforward to see how this form of primacy can be derived from the Fundamental Principles in Articles 3-7. However, given that the *Declaration* sets out principles which acknowledge that ‘human beings have responsibilities and duties towards other forms of life in the biosphere’ (*Article 1 – Scope*), it would appear helpful to offer some guidance on the relationship between humans and animals and their relative status. This in turn would suggest that a Fundamental Principle on the matter would be required.

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAËL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“Any decision or practice ~~within the scope of this Declaration~~ shall be founded on the recognition of the primacy of the **individual** human person, which shall prevail over the [sole] interest of science or society [*alternative formulation*: “...shall **respect the principle that the interests and welfare of the individual human person shall prevail over the sole interest of science or society**”].”

Article 10 - Autonomy and Responsibility

COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) / BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)

Titre : « Droit à l’information, autonomie et responsabilité »

Ajouter une phrase : « *Il en découle que la personne doit bénéficier au préalable d’une information adéquate et complète afin de pouvoir exercer cette autonomie* ».

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAËL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“...within the confines of the limits of autonomy set as a form of exercising justice according to domestic law.”

COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) / NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)

« Toute décision ou pratique relevant de la présente Déclaration doit respecter l’autonomie de la personne comme étant l’expression de sa liberté de prendre des décisions ~~sans porter atteinte à l’autonomie d’autrui~~ **pour autant que l’expression de cette autonomie n’ait pas de conséquences néfastes pour la communauté.** »

Article 11 - [Informed] Consent

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAËL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“a) The prior, free, informed and express consent of the persons concerned shall be obtained in all medical or scientific research, treatment or diagnosis. Such consent may be withdrawn at any time, **while always upholding the best interests of the person concerned.**”

**COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) /
NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)**

« a) Le consentement préalable, libre, éclairé et exprès des personnes, **familles ou groupes** concernés doit être obtenu pour toute recherche médicale ou scientifique et pour tout traitement ou diagnostic. Ce consentement peut être retiré à tout moment. »

**COMITÉ NATIONAL NORVÉGIEN POUR L'ÉTHIQUE DE LA RECHERCHE MÉDICALE (NORVÈGE) /
NORWEGIAN NATIONAL COMMITTEE FOR MEDICAL RESEARCH ETHICS (NORWAY)**

Article 11 a) emphasizes the principle of a prior, free, informed and express consent as a condition for all medical research, treatment and diagnostic activities. We, of course, acknowledge this principle as the main basis for the inclusion of human subjects in medical research, and that there must be important reasons to depart from this requirement. However, there are situations when informed consent is impossible, impractical or even unadvisable to obtain. Examples can be research in emergency situations, epidemiological research or research on archived materials. In such cases it may be more relevant to base the research on alternative consent procedures or exempt from consent provided the project has been reviewed by an independent ethics committee. The point is that by phrasing article 11 a as suggested in the third draft, it appears that there are no exceptions to the principle of a free, informed and specific consent. This is exactly the kind of detailed prescription that must be avoided in a universal declaration. We have used article 11 as an example to emphasize the problems involved when the text in a universal declaration becomes too detailed and action oriented. The same objections may also apply to other articles in the draft.

NUFFIELD COUNCIL ON BIOETHICS

It would be desirable if important developments which have arisen from the considerable discussion about the concept of 'informed consent' could be reflected in the Declaration. We make three observations concerning: (a) the question of whether informed consent is pragmatically feasible and a sufficient criterion for involving participants in research; (b) the special case of consenting to the use of tissue or data for research purposes; (c) the question of whether consent is necessary for *all* medical or scientific research, treatment or diagnosis.

First, while the provision of information in obtaining consent is important, it should be noted that the ethically significant requirement of consent is not that it be complete, but rather that it be genuine, as, for example, the Council has described in several of its Reports.⁴ Consent can be given to some course of action such as an operation, donation, participation in medical or scientific research, only as described in a specific way. Since description can never be fully exhaustive, consent will always be to action that is incompletely described. Moreover, the descriptions offered are often incompletely understood. This incompleteness cannot be remedied by devising more elaborate consent forms, and fully informed consent is usually an unobtainable ideal.

Ensuring that consent is genuine is mainly a matter of care in detecting and eliminating lack of consent. Obtaining genuine consent requires researchers and medical practitioners to do their best to communicate accurately as much as patients, volunteers or relatives can understand about procedures and risks, and to react to the limits of their understanding, and of their capacities to deal with difficult information. This is of particular relevance with regard to research undertaken in developing countries. If all reasonable care is exercised, adequate and genuine consent may be established, although it will necessarily fall short of fully informed consent. Rather than simply reiterating the unobtainable ideal of 'informed consent' the *Declaration* should therefore acknowledge the shortcomings of the concept and highlight the importance of the *process* of obtaining consent.

Secondly, the current drafting of Article 11 is ambiguous in relation to what research participants are required to consent *to*. Is it only their immediate participation in 'medical or scientific research, treatment or diagnosis', or also the use of tissue removed from them during such practices, or the use of patient-related medical data? If the latter two categories are intended to be covered, Article 11 could be interpreted as stating that *each* use of a set of data, or tissue removed from a patient, requires individual consent from that patient. This would be a problematic provision. It is sometimes desirable to use the samples taken for

specific purposes for other types of research at a later stage. Obtaining renewed consent can be difficult, especially if large numbers of people are involved, or if there is some time between the taking of the initial sample and the interest in its renewed use for research. In response to this problem, the concepts of ‘broad’ and ‘narrow’ consent have been developed. The latter refers to instances where a sample is only to be used for one single, or a restricted range of purposes, perhaps only for a specific research project, or for research in relation to one particular medicine or condition. Broad consent entails that patients agree that their sample may be used for a variety of future studies which cannot be specified in detail at the time of obtaining consent. Usually, but not always, these future studies will be within the same broad areas of research as the initial project. In order to avoid future misunderstandings, it would be useful to state in Article 11 whether or not broad consent is acceptable. It would also be useful to clarify the implications of the sentence: ‘Such consent may be withdrawn at any time.’ Presumably, the assumption underlying this phrase is that once consent has been withdrawn, the person concerned ceases to take part in medical or scientific research, treatment or diagnosis, and also that samples or data obtained during such activities must no longer be used. However, as recognised in UNESCO’s International Declaration on Human Genetic Data (Art 9 (a) (b)), it will sometimes only be possible to offer a limited range of options for withdrawal of consent to the use of tissue or personal medical data. It would be useful if the *Declaration* acknowledged this point.

Thirdly, there has also been discussion about whether consent is necessary for all types of research. In the UK, the Human Tissue Act (2004) provides that the secondary use of anonymised tissue samples will not require (legal) consent, provided other safeguards are put in place to ensure that the interests of participants in research are protected. Such provisions are of particular importance for the purpose of monitoring public health. The consequences of requiring consent for *all* purposes therefore need to be considered carefully in Article 11. (With regard to public health it would also be helpful to clarify whether ‘research’ includes activities such as surveillance or monitoring of public health.)

In view of these observations we therefore suggest the following re-wording of Article 11 (a):

“Prior, free, and genuine consent shall be obtained from those participating in medical or scientific research, treatment or diagnosis. Separate consent may be required for the use of tissue or data obtained from persons during such practices. With regard to consent for the use of tissue or medical data, in some cases ‘narrow consent’ may be appropriate (limiting the consent to one single purpose, or a small range of purposes). In other cases ‘broad consent’ may be appropriate (extending the consent to the use of tissue or medical data in future studies, the particulars of which may not be possible to specify in detail at the time of obtaining consent). For consent to be genuine, it is crucial that care is taken in detecting and eliminating lack of consent. Consent may be withdrawn at any time, and the options and consequences of withdrawing consent for the use of data or tissue samples from research shall be explained in the consent process.”

SCOTTISH COUNCIL ON HUMAN BIOETHICS

Para (a): Is the provision of artificial nutrition and/or hydration to a patient considered as a treatment?

Para (b): What if the person does not have a legal representative?

Article 12 – Privacy and Confidentiality

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“Any decision or practice ~~within the scope of this Declaration~~ shall be made or carried out with ~~full~~ respect for the privacy of the persons concerned and the confidentiality of their personal information. Such information cannot be used or disclosed for purposes other than those for which it was collected, except with the **prior, free, informed and express** consent of the person concerned or ~~for compelling public interest reasons~~ in cases restrictively provided for by domestic law consistent with international human rights law, **for reasons of justice, public security, health, safety and essential well-being.**”

Article 13 - Sharing of Benefits

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAËL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

~~“In accordance with international and domestic law, a)~~ **Benefits** resulting from scientific research and ~~their~~ **its** applications should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms:

...

- (v) access to scientific and technological knowledge, ~~in particular~~ **in accordance with local conditions, including those of developing countries;**”.

COMMISSION NATIONALE DE BIOÉTHIQUE (MEXIQUE) / NATIONAL COMMISSION OF BIOETHICS (MEXICO) (DRAFT #7 REV.)

Un comentario adicional en cuanto a los beneficios y su distribución. Consideramos pertinente hacer hincapié en que lo que se conoce como benefit sharing, tiene una connotación particular para los países en desarrollo; la lectura más adecuada, sería el de poder ser colaboradores auténticos, tanto en el diseño como el desarrollo de los protocolos de investigación y de los diversos desarrollos.

PROCEDURAL PRINCIPLES

COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) / BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)

Titre : « Principes d’application ».

NUFFIELD COUNCIL ON BIOETHICS

The status of these principles is not clear. Are the procedural principles envisaged as a separate set of Fundamental Principles, differing only in that they relate to procedural issues? Alternatively, are they supposed to be derivable from the Fundamental Principles in the same way as the principles listed under Articles 8-13?

Article 14 - Honesty and Integrity

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAËL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

“Any decision or practice ~~within the scope of this Declaration~~ shall:

- (i) be ~~conducted~~ **made or carried out** with **professionalism**, independence and intellectual honesty;.....”.

COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) / NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)

Il y a lieu de noter qu’aujourd’hui toute recherche notamment dans le domaine du génie génétique suscite forcément des incertitudes sur l’avenir de l’humanité et nécessite dès lors des débats approfondis préalablement à sa mise en œuvre. Sans pour autant remettre en cause l’indépendance dans la conception et l’initiation d’une recherche, et nonobstant l’existence de l’article 18 qui se limite aux questions suscitant des divergences, nous proposons que l’alinéa (i) de cet article en ce qui concerne les protocoles de recherche, soit libellé comme suit : « (i) être mise en œuvre en tout honnêteté intellectuelle **et doit tenir compte de la nécessité d’être préalablement examinée par un comité d’éthique pluridisciplinaire et pluraliste** ».

Article 16 - Scientific and Rational Methods

COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) / BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)

Titre : « ~~Méthodes~~ **Méthodologies** scientifiques ».

**COMITÉ NATIONAL DE BIOÉTHIQUE (RÉPUBLIQUE DÉMOCRATIQUE DU CONGO) /
NATIONAL BIOETHICS COMMITTEE (DEMOCRATIC REPUBLIC OF CONGO)**

A l'alinéa (iii), la notion de « certains principes » gagnerait à être précisée, et notamment par la sécurité des sujets humains impliqués dans la recherche.

Article 17 - Community and Expert Consultation

**COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) /
BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)**

Troisième ligne : « ...de revoir régulièrement l'état de ces connaissances et d'évaluer les divergences... » .

PROCEDURES

Article 21 - Ensuring Public Debate

**COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) /
NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)**

“States should ensure that citizens have an opportunity for informed, pluralistic public debate, ensuring the participation of **representatives of all the relevant views and interests** ~~all the stakeholders~~ concerned ~~and the~~, **including** relevant bioethics committees **and non-governmental organizations**, and the expression of various socio-cultural, religious and philosophical opinions.”

Article 22- Transnational Practices

**COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) /
BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)**

Remplacer « devrait » par « **doit** ».

[SPECIFIC ISSUES]

**COMITÉ CONSULTATIF DE BIOÉTHIQUE (BELGIQUE) /
BIOETHICS CONSULTATIVE COMMITTEE (BELGIUM)**

Nous proposons de ne pas traiter des sujets spécifiques dans la déclaration universelle sur la bioéthique.

**COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) /
NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)**

Specific Issues: not to be included in such general Declaration.

**CONSEIL DE LA RECHERCHE EN MATIÈRE DE SANTÉ (NOUVELLE ZÉLANDE) /
HEALTH RESEARCH COUNCIL (NEW ZEALAND)**

In our last comments we responded that including a small number of areas where there is unequivocal consensus would be a starting point to ensure continuing support to build on consensus in other challenging areas. We continue to consider this to be an important consideration however, on review of the third draft, we are of the view that this support can be gained from the general principles included.

In addition, we would like to highlight the possible negative effects arising from the inclusion of certain central topics which may be elaborated on in other texts at a later stage. It is our view that clarity and the greatest degree of simplicity appropriate are of utmost importance in the development of international declarations which seek to be used and applied. In the

context of both existing (such as the *International Declaration on Human Genetic Data*) and possible new declarations on specific topics, we consider it would be best to clearly distinguish the status of the future declaration as a general text, sitting above other declarations on specific subjects (which will be consistent with it) and applying to all areas. Further, we consider that the possible existence of guidance on specific topics in more than one source, (for example, in both the future declaration on universal norms in bioethics and a declaration on a specific subject) may be confusing and will be superfluous.

If certain central topics are to be included on the basis that they will provide illustration on the application of the principles set forth in the future declaration with a view to their application to other fields, as suggested in paragraph 27. of the Final Report of the IBC drafting group's fourth meeting, we are of the view that the text should clearly reflect this intention, and central topic should be distinct from the other general principles of the future declaration.

NUFFIELD COUNCIL ON BIOETHICS

In previous draft versions of the Declaration, this section included a relatively comprehensive list of specific issues to which the principles set out in the draft Declaration could be applied. The present draft does not include any of these issues, which makes it somewhat difficult to comment on whether or not it would be useful to include specific issues in the Declaration. This omission raises a number of questions: should the Declaration address any specific issues? If so, which issues should be selected, and how should these be addressed? We make some general observations in relation to some possible scenarios:

- a) the Declaration does not address any specific issues; the section will be deleted;
- b) the Declaration does not address any specific issues, but a general provision is included to the effect that specific issues will be addressed in separate Annexes to the Declaration, or in separate Declarations altogether;
- c) the Declaration does not address any specific issues, but a general provision is included to the effect that specific issues will be addressed in separate Annexes to the Declaration, and these issues are listed in the Declaration;
- d) the Declaration addresses a few particularly important issues (for example research involving human participants, organ donation, and others), and a qualification is made that contentious areas of research or development which are not included (for example stem cell research, nanotechnology, and others) are therefore neither acceptable, nor unacceptable under the Declaration;
- e) the Declaration addresses an exhaustive list of specific issues.

Option (a): According to this option, the primary function of the Declaration would be to provide a useful high-level framework which would set out aspirational ideals. Policy makers could use the framework as a reference point for the formulation of national and international legislation. By not addressing specific issues, confusion about whether or not the *Declaration* should be transposed directly into national law would be avoided (see the discussion about the status of the *Declaration of Helsinki* in the Council's first submission). On a more pragmatic level, and in view of the IBC's tight timetable, this option would allow for discussion of open questions about the general structure and content of other sections of the Declaration, raised, for example, in this submission. Focussing on a high-level framework would also be valuable for achieving consensus among UNESCO member states and other stakeholders, while being sensitive to cultural differences.

Option (b): This modified version of option (a) would allow the IBC to address more specific issues in light of the provisions of the general Declaration at a later stage, and with sufficient time. However, different drafting committees of the various Annexes could interpret the provisions of the general Declaration differently, which might lead to inconsistency. An alternative option might be for the IBC to consider a range of specific issues in separate Declarations, in parallel to the already published documents *The Universal Declaration on the Human Genome and Human Rights* and the *International Declaration on Human Genetic Data*.

Option (c): This scenario would have the advantage of offering transparency with regard to the type of Annexes which are planned. In listing those areas to be addressed it might also be possible to state which of the Fundamental, Derived, Procedural or other principles are

important in which areas. However such a list is likely to be repetitive. Furthermore, it is not straightforward to establish a finite list of specific issues which will be addressed in the Annexes, as new technologies continually arise, and pose new ethical challenges.

Option (d): In this scenario, the difficulty of distinguishing those areas which merit discussion under the *Declaration* is acknowledged. Only a few particularly important areas are therefore addressed within the Declaration, leaving open the possibility of considering further areas in Annexes or separate Declarations. In selecting those specific issues which could be addressed in the Declaration, it would seem useful to take into account UNESCO's international role, and to focus on issues with global dimensions, such as research involving human participants, organ transplantation, or access to healthcare. Issues mainly of relevance to developed countries, such as stem cell research or nanotechnology, could be given a lower priority. However, even if such a restriction were thought to be useful, it would seem necessary to clarify the relationship between the provisions of the Declaration and those of already established guidance, for example the *Declaration of Helsinki*, or the CIOMS Guidelines. This option is therefore likely to pose considerable conceptual and pragmatic difficulties. It is questionable whether it would be possible for the IBC to pursue this option within the envisaged timeframe, as appears to have also been acknowledged during discussion of the *Declaration* at the 170th session of the Executive Board.⁵

Option (e): While, in principle, this option would allow for a coherent discussion of a range of different specific issues in light of the provisions of the Declaration, time constraints alone suggest that this is not feasible. Furthermore it is questionable how desirable a 'complete' Declaration is, if new emerging technologies continue to pose new ethical problems.

In view of these observations we recommend that options (a) or (b) be pursued. In our opinion, from both a conceptual and a pragmatic point of view, these options are superior to the others, and any derived options.

PROMOTION AND IMPLEMENTATION

Article 24 - Solidarity and International Cooperation

COMITÉ NATIONAL DE BIOÉTHIQUE (ISRAEL) / NATIONAL BIOETHICS COMMITTEE (ISRAEL) (DRAFT #8)

~~b)~~ a) States should foster ~~the~~ international dissemination of scientific information and make every effort to guarantee the free flow and sharing of scientific and technological knowledge [~~namely~~ **including through** the creation of research and education structures in the developing countries as well as the transfer of technology].

⇒ b) In the framework of international cooperation, States should promote cultural and scientific cooperation, endeavouring to enter into bilateral and multilateral agreements enabling **all** countries, **including** developing **countries**, to build up their capacity to participate in generating and sharing scientific knowledge, ~~and of~~ the related know-how *and the benefits thereof*."

Article 29 - Restrictions

NUFFIELD COUNCIL ON BIOETHICS

It would be important to clarify exactly which principles may be restricted by law. Presumably it is not intended to allow for the possibility that the Fundamental Principles can be restricted by law? If so, does the possible restriction only relate to the derived principles, and/or the procedural principles? Additionally, in reviewing the wording of Article 29 we would also recommend that account be taken of the nuanced provisions in Article 8(2), 9(2), 10(2), and 11(2) of the *European Convention for the Protection of Human Rights and Fundamental Freedoms*, which concern the degree to which the law may restrict rights in specific areas.

Part / Partie V

Contributions à titre personnel / Individual contributions

- **Mme / Mrs Brenda Almond** (Royaume-Uni / United Kingdom)
Membre de la Commission de génétique humaine /
Member of the Human Genetics Commission
- **M. / Mr Abdulaziz Mohammed Al-Swailem** (Arabie Saoudite / Saudi Arabia)
Directeur à la King Abdulaziz City for Science and Technology (KACST) /
Director at the King Abdulaziz City for Science and Technology (KACST)
Ancien membre du CIB / Former member of IBC
- **M. / Mr Nigel Cameron** (Etats Unis d'Amérique / United States of America)
Professeur de bioéthique / Professor of Bioethics
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Institute on Biotechnology and the Human Future of the Illinois Institute of Technology
- **M. / Mr José-Maria Cantu** (Mexique / Mexico)
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- **M. / Mr Hubert Curien** (France)
Ancien ministre de la recherche scientifique / Former Minister of Scientific Research
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GENERAL COMMENTS

Abdul Aziz Al-Swailem

We are keen to consider the future declaration as a text that proclaims general principles (including procedures) in the field of bioethics, with concrete subjects to be dealt with in other texts, taking into account the stated principles and the reports already produced by IBC on specific issues.

José María Cantu

The future declaration should set forth the right of access to health care services as an indispensable condition to improve the quality of life.

Anne McLaren

The terminology should be consistent throughout the text (in particular the reference to principles and to human beings/persons)

Sylvia Rumball

I like the classification into fundamental, derived and procedural principles. I find that very helpful and have already used the concept in some developmental work that I am involved in (with Professor Don Evans) in my role as member of an Ethics Advisory Panel for the New Zealand Environmental Risk Management Authority. Further in another forum I have reviewed the concept with members of our University's Human Ethics Committees in relation to the University's Code of Ethical Conduct for Research with Human Participants. Members reported that it provided a clarification to their thinking that they welcomed and we agreed that we would revisit the way the principles in the University's Code were presented and incorporate the approach used in the draft Declaration.

No doubt there will be a range of opinions over what is fundamental and what is derived. The principles in Article 4 and 5 could be argued to be derived principles. My preference is that the number of fundamental principles be as small as possible.

TITLE

John Williams (Draft #7 Rev.)

“Declaration on Bioethics”

PREAMBLE

John Williams (Draft #7 Rev.)

I strongly support the new opening paragraphs added in this version. They provide a much better introduction to the document than the listing of existing instruments.

The first paragraph should be divided into two, because it contains two distinct, and important, ideas: (1) scientific and technological developments, and (2) the need for a global response. Globalization, whether of science and technology or of ethics, is a major reason why this document is being produced and this should be made clear in a separate paragraph.

In the first paragraph, and elsewhere in the document, it is stated or implied that the major source of bioethical issues are developments in science and technology. I would say that equally important are developments in other spheres of human activity such as human rights, politics (democracy) and individual and community self-empowerment.

One thing that the draft Declaration lacks is a clear indication of the sources of its principles. Presumably they come from the documents listed in the preamble. If that is the case, than is the introductory word “Recalling” sufficient? I wonder whether there should be a stronger statement connecting these instruments to the principles in this document.

I appreciate the reference to other international and regional instruments in the field of bioethics. Two modifications of the proposed text are in order: (1) “the international, **national** and regional codes of conduct and guidelines”, since most applicable codes of ethics for the health professions are national; and (2) the dates of adoption and amendment of the

Declaration of Helsinki should be deleted, since it is a living document and can be updated at any time (in fact, there was no amendment in 2002, just the addition of a note of clarification, and another note of clarification was added in 2004)

The paragraph beginning, “Considering also that it is the mission of UNESCO”, is long and complex. It could easily be divided in two. I looked at the UNESCO website and did not find any confirmation about the mission as described here. Moreover, not all questions of bioethics, for example, in clinical bioethics, have an international dimension.

In the following paragraph, the Drafting Group suggests adding the words, “and societal”, after “ethical”. This raises the question, what is the difference between the two? Surely societal reflection can be ethical. Perhaps that is what is intended by the addition but it is ambiguous.

The following, new, paragraph would read better as follows: “Recognizing that bioethical issues affect individuals, families, groups or communities and humankind as a whole.”

In the paragraph beginning, “Convinced that ethical reflection”, the words, “issues arising from” can be deleted. Ethical reflection is needed at all stages of scientific and technological development, including before it begins.

In the following, new, paragraph, the words, “resulting from”, seem inappropriate in the context. Here, as elsewhere, there is an attempt to combine several ideas in one paragraph with the result that the overall intention is not very clear. Perhaps it would be better simply to delete the words, “that the social responsibility resulting from bioethics requires”.

Nigel Cameron

Under the recitals, the second or third paragraph “also recalling” should include reference to the Hippocratic Oath, the Nuremberg Code, the Declaration of Helsinki, and the Declaration of Geneva, which are the key waymarks in medical ethics. Their absence from the draft is both puzzling and potentially disturbing. It is vital to root the contemporary discussion in these great declarations of the humane medical tradition.

[USE OF TERMS] (LIMITED TO SCIENTIFIC TERMS)

Qiu Ren-Zong

What is the difference between human beings and human person? In Chinese language there is no difference. If we use these two terms, these should be listed in the Use of Terms which should not be limited to scientific terms.

John Williams (Draft #7 Rev.)

Definition of bioethics – this is crucial and to my mind is unclear. It is not obvious that “the life sciences” include health care practice, which is clearly a major concern of bioethics. It needs to be stated clearly here whether the Declaration does, or does not, deal with issues in medicine and health care more generally. One small point – “involving” should be replaced by “of”.

GENERAL PROVISIONS

Article 1 - Scope

John Williams (Draft #7 Rev.)

The Drafting Group’s proposal to eliminate “human beings” at the beginning of the first paragraph is problematic since individuals, families and groups can be non-human. This paragraph contains two distinct ideas, which should be separated.

Qiu Ren-Zong

“Human beings have responsibilities and duties towards **non-human animals** and other forms of life in the biosphere,” (in view of the closer relationship with non-human animals).

Article 2 - Aims

Abdul Aziz Al-Swailem

“- to provide universal **guidelines** of fundamental principles and basic procedures designed to guide States in the formulation of their legislation and their policies in the field of bioethics, and to form the basis for guidelines in bioethical matters for the institutions, groups and individuals concerned;.....

- to ensure the respect for human dignity and the protection of human rights and fundamental freedoms in [the sphere of] bioethical decision making, in accordance with human rights ~~law~~.”

John Williams (Draft #7 Rev.)

Para. 1 – substitute “global” for “universal”.

Para. 2 – substitute “promote” for “ensure”. The Declaration cannot ensure these things.

Paras. 3, 6 and 7 – these are worthy aims, but how will the Declaration achieve them?

Para. 4 – the words at the end, “and to prevent practices contrary to human dignity”, doesn’t fit here grammatically (or otherwise).

GENERAL [FUNDAMENTAL] PRINCIPLES

Abdul Aziz Al-Swailem

Add a new article: “**The ultimate of any research activity should not be of any harm for person, group, trip or race and it should be for the general welfare of the human race and environment**”.

John Williams (Draft #7 Rev.)

Suggestion for the headings: “Basic Principles”. General implies specific; fundamental is better but perhaps overstates what follows.

Albie Sachs

Reference should be made somewhere to the objective of the alleviation of suffering and the enhancement of the quality of life.

Article 3 - Human Dignity, Human Rights and Justice

Abdul Aziz Al-Swailem

“Any decision or practice within the scope of this Declaration shall be made or carried out with full respect for **the life, mind, paternity purity and** inherent dignity of the human person, human rights and fundamental freedoms and for the universal principle of justice.”

John Williams (Draft #7 Rev.)

What is “the universal principle of justice”? How is it related to human dignity and human rights?

Article 4 - Beneficence and Non-Maleficence

Abdul Aziz Al-Swailem

“Any decision or practice within the scope of this Declaration shall seek to optimize [maximize] the benefits and minimize the possible harms of such decision or practice [to the persons concerned, **others and society**].”

Or delete the sentence in brackets i.e. [to the persons concerned] in the original text.

Nigel Cameron

This statement interprets beneficence and non-maleficence in terms that are utilitarian and that wrench them from their context in the humane Hippocratic tradition. I would rather it be omitted than appear like this. They should be restated in absolute terms as statements of the purposes of medicine, and of the life sciences in the service of medicine.

Abdul Aziz Al-Swailem

“Any decision or practice within the scope of this Declaration shall take into account the cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious beliefs and like considerations. However, cultural diversity [**such considerations not rotted in religious believe**] shall not be invoked to infringe upon the universal principles set out in this Declaration, nor to limit their scope.”

Or delete the sentence in brackets i.e. [such considerations] in the original text.

Brenda Almond

Possible rewording: “**While recognising the diversity of [people’s] cultural backgrounds, schools of thought, value systems, historical and philosophical traditions, religious beliefs and like considerations, such considerations shall not be invoked to infringe upon the universal principles set out in this Declaration, or to limit their scope.**”

Article 6 - Solidarity, Equity and Cooperation**Abdul Aziz Al-Swailem**

“Any decision or practice within the scope of this Declaration shall respect the solidarity of humanity, ensure equity and encourage international cooperation [, in order *inter alia* to avoid discrimination and stigmatization of an individual, a family, **tribe, race** or a group].”

John Williams (Draft #7 Rev.)

If the Declaration applies to clinical medical practice, then these requirements are impossible to fulfil in every encounter between a patient and a health care professional. Perhaps change “take into account” in article 6 and “respect” in article 7 to “have due regard for”.

Oiu Ren-Zong

Use stronger wording on stigmatization and discrimination, such as: “**Stigmatization and discrimination against any individual, family and group shall be prevented.**”

DERIVED PRINCIPLES**Article 8 - Primacy of the Human Person****Abdul Aziz Al-Swailem**

“Any decision or practice within the scope of this Declaration shall be founded on the recognition of the primacy of the human person **taking in consideration protecting the right and welfare of the unborn (i.e. fetus) and future generation**, which shall prevail over the [sole] interest of science or society.”

John Williams (Draft #7 Rev.)

Why is this a derived rather than a basic/fundamental principle? The words, “the recognition of”, seem unnecessary.

Oiu Ren-Zong

In it human person is opposed with interest of science and society. However, human person v. interest of science and human person v. interest of society are different. In any case human person should be preeminent over interest of science, unless the risk to human person is minimal and reversible and free informed consent is obtained. However, in many cases

interests of society may include, or be compatible with the interest of a human person. In the case of SARS or plague, individual person has to be isolated or quarantined this is in her/his best interest as well as in the best interest of other persons and the society.

Article 9 - Non-Discrimination and non-Stigmatization

Abdul Aziz Al-Swailem

“..., nor shall such conditions or characteristics be used [invoked] to stigmatize an individual, family, group, **race or society**.”

Brenda Almond

“Discrimination” must be qualified as “**unjust**” or “**arbitrary**”.

Nigel Cameron

This statement should be explicitly headed “**Genetic discrimination**” and address that question more directly.

Article 10 - Autonomy and Responsibility

John Williams (DRAFT #7 REV.)

The text of this article deals with autonomy but not responsibility. Perhaps replace “an expression” by “**the foundation**”.

Qiu Ren-Zong

Here responsibility is not fully described. Autonomy implies responsibility.

Brenda Almond

Clearer to replace “without prejudice to” with “**that do not prejudice**”.

Article 11 - [Informed] Consent

Abdul Aziz Al-Swailem

“b) When, in accordance with domestic law consistent with international human rights law, a person is incapable of giving consent, such consent [authorization] should be obtained from his / her **authorized** legal representative, having regard to the best interest of the person concerned.”

John Williams (DRAFT #7 REV.)

Para. a) is not consistent with international standards of medical ethics. “Prior” consent cannot always be obtained, for example, in emergency situations. “Express” consent is not always required; for many simple procedures (e.g., measuring blood pressure) implied consent is perfectly adequate. Diagnosis generally comes before treatment.

Para. b) should be reorganized as follows: “**When a person is incapable of giving consent, authorization for diagnosis or treatment should, if possible, be obtained from his/her legal representative, in accordance with domestic law consistent with international human rights law, and having due regard to the best interests of the person concerned.**” Participation in research of individuals incapable of giving consent is very complex and controversial and it would be better not to try and make a definitive statement about it here.

Qiu Ren-Zong

Consent should be informed. Special protection should be given to “incapable” (physically) and “vulnerable” (socially).

Brenda Almond

a) “Such consent may be withdrawn at any time”. This is impractical where a procedure, e.g. a surgical procedure is already in progress. There may also be a specific problem in relation to the rules regarding transfer of ova or embryos in infertility treatment where consent applies only until they are being used in treatment

b) “having regard to the best interest of the person concerned”. I suggest adding “or their prior expression of views, including moral views, that relate to their treatment”. I have in mind here a person suffering from dementia who has expressed a prior wish to be treated in a way which at that later time may NOT be judged by others to be in their best interest. This might, for example, include aggressive treatment of medical conditions.

PROCEDURAL PRINCIPLES**Article 14 - Honesty and Integrity****John Williams (Draft #7 Rev.)**

Para. (i) – to be consistent, the wording of article 4 should be used, i.e., “**any decision or practice should be made or carried out**” (this applies to the articles that follow).

Para. (ii) – “respect the need” is inappropriate and should be changed.

Para. (iii) – conflict of interest cannot always be avoided; in such cases it needs to be resolved.

Qiu Ren-Zong

Either honesty or integrity is not a procedure, they are virtues a scientist or an institute should have. Better to put them in the General Principles.

Conflict of interest should be in an independent article, because it is very serious problem in scientific research and application now.

Article 16 - Scientific and Rational Methods**Abdul Aziz Al-Swailem**

(iv) observe, when appropriate, proper procedures of risk assessment; and

Delete (v).

John Williams (Draft #7 Rev.)

Para. (v) – the final clause, “allowing for...,” is too permissive. Perhaps add something like, “**subject to the other principles of this Declaration**”.

Article 17 - Community and Expert Consultation**John Williams(Draft #7 Rev.)**

Para. (ii): change “members” to “**representatives**”.

Qiu Ren-Zong

Article 17 be divided into two:

- Article on Community: community involvement, responsibilities to community, share benefits from scientific progress;
- and Article on Expert Consultation.

Article 18 - Fair Decision-Making Process

Abdul Aziz Al-Swailem

“Any decision or practice within the scope of this Declaration, where differences arise, shall be resolved following full and free discussion and in accordance with **local law and fair procedures.**”

John Williams (Draft #7 Rev.)

This should be retitled, “**Fair Conflict Resolution Process**”. The other procedural principles in this section deal with elements of a fair decision-making process. The paragraph could be reworded as follows: “**Where differences regarding any decision or practice arise, they shall be resolved in accordance with fair procedures**”.

One important procedural principle that is missing is “accountability”.

Qiu Ren-Zong

“**Democratic Decision-Making Process**”: In view of the development and application of science and technology which would have more and more important impact on human life, the decision should be made in a democratic way, and a mechanism of involving the public, NGO or organizations of civil society in decision-making process be designed.

PROCEDURES

Article 19 - Risk Assessment

John Williams (Draft #7 Rev.)

What does “provisional adequate and proportionate measures shall be taken in a timely manner” mean here?

Article 20 - Ethics Committees

John Williams (Draft #7 Rev.)

This paragraph does not make the necessary distinctions between various types of ethics committees (research, clinical, political). The functions stated in paras. (i) and (ii) are appropriate for some ethics committees but not for others, e.g., clinical ethics committees. Research ethics committees fulfil the first function but not the second.

Article 21 - Ensuring Public Debate

Abdul Aziz Al-Swailem

“**Through appropriate channels, States should ensure that...**”.

Article 22- Transnational Practices

John Williams (Draft #7 Rev.)

This paragraph gives the impression that there is just one type of transnational practice that requires bioethical consideration, i.e., research. There are other major transnational bioethical issues, e.g., organ sales, assisted reproduction, etc.

[SPECIFIC ISSUES]

John Williams (Draft #7 Rev.)

I agree that this section should be omitted and that specific topics be dealt with in other documents. The alternate proposal, that certain subjects such as health and scientific research be included, is impractical, given the timetable for this project. Moreover, there are already enough international documents on medical research.

Sylvia Rumball

With regard to the inclusion or not of specific subjects, my preference is that specific subjects be dealt with in other texts. This will assist the clarity of this text and make the role of the Declaration more clear. Including some subjects but omitting others runs the risk of indicating there is a hierarchy of importance with respect to the application of ethical principles. I would prefer that there was a clear indication that the Universal Declaration is indeed universal in its application as opposed to being selectively applicable.

PROMOTION AND IMPLEMENTATION**Article 23 - Bioethics education, training and information****John Williams (Draft #7 Rev.)**

Para. a): politicians and civil/public servants should be added to the list of target audiences.

Nigel Cameron

Article 23(b): A reference should be added to the special role of religious and other civil society organizations, to make explicit what could be taken to be implicit in the reference to NGOs. Religious organizations have an especially important role to play in bioethics education.

Article 24 - Solidarity and International Cooperation**John Williams (Draft #7 Rev.)**

Although the sentiments expressed in this article are admirable, they are not specifically related to bioethics nor do they speak to the promotion and implementation of the Declaration.

Article 25 - Role of States**John Williams (Draft #7 Rev.)**

Para. c): what risks are meant here? This needs to be much more specific.

Article 26- Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)**John Williams (Draft #7 Rev.)**

Para. a): why “should” instead of “shall” in the last three sentences?

Article 27 - Follow-up action by UNESCO**John Williams (Draft #7 Rev.)**

Why just “new” developments? Many current practices need regular review. And why just developments “in science and technology”? Societal, and especially ethical, developments are also important.

Article 29 - Restrictions**Abdul Aziz Al-Swailem**

“No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by **local** law in the interest of public safety.....”.

John Williams (Draft #7 Rev.)

This paragraph, especially the words, “in the interest of public safety, for the prevention of crime”, provides an enormous loophole to States to ignore the provisions of the Declaration. At the very least, it should come after and be subject to article 31, but I would prefer that it be deleted.

Albie Sachs

I am concerned that any restriction should not simply be prescribed by law for the identified purposes, all of which I support. There should be a restriction on these restrictions. I would strongly support that they be necessary in a democratic society and involve the least degree of restriction necessary. It is necessary, for example, to avoid authorising the adoption of a law for the protection of the property rights of others in a way which would cut right across the whole thrust of the Text.