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**Second Session of the Intergovernmental Meeting of Experts
Aimed at Finalizing a Draft Declaration on Universal Norms on Bioethics**

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

**COMPILATION OF PROPOSED AMENDMENTS
SUBMITTED BY MEMBER STATES**

This document compiles proposed amendments to the Preliminary Draft Declaration on Universal Norms on Bioethics received in writing from Member States as of 6 June 2005 with a view to the second session of the intergovernmental meeting of experts aimed at finalizing a draft declaration (Paris, 20-24 June 2005).

It also includes the written, and as far as possible, oral amendments concerning Articles 1 to 10 proposed during the first session of the intergovernmental meeting of experts (Paris 4-6 April 2005).

The proposed amendments are divided into three categories: (A) Additions, (D) Deletions and (M) Modifications. Comments (C) on specific articles are also presented.

Division of Ethics of Science and Technology

GENERAL COMMENTS

<p>AUSTRALIA</p>	<p><i>Australia considers that the draft declaration can provide a useful tool to States by setting out the basic procedures needed to formulate legislation and policy in the field of bioethics. In general, Australia considers the approach taken by the IBC and subsequently to minimise references to specific instances of bioethics is appropriate because a broader set of guiding principles, outlining the general approach to bioethics issues, will prove useful and relevant into the future as science and technology develops.</i></p> <p><i>While the draft Declaration offers an opportunity to provide guiding principles for the governing of bioethics issues, we consider that the text should be of a voluntary, non-binding nature, take into account differing approaches to bioethics and refer to domestic legislation and pre-existing international law. For this reason, we attach particular value to Article 31 which acts as a safeguard to ensure that nothing in the draft impinges on human rights, fundamental freedoms or human dignity. As we would not want to see the creation of new obligations, we would be opposed to mandatory and legally binding language, particularly in relation to the provision of new and additional resources.</i></p> <p><i>Australia also supports an approach which avoids creation of new obligations or the amendment of existing ones in relation to access and benefit-sharing regimes. The issues of access to genetic resources and benefit sharing in relation to the use of such resources are being discussed in a wide range of national and international fora such as discussions in the context of one of the key objectives of the Convention on Biological Diversity namely the ‘fair and equitable sharing of benefits arising out of the utilization of genetic resources’ (Article 1) and in the World Intellectual Property Organisation Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.</i></p>
<p>GERMANY</p>	<p><i>The scope question is decisive for the quality of the whole declaration, which in our view should become a fundamental globally relevant document with the capacity to establish common bioethical standards and foster their global implementation. In this perspective, attempts to widen the scope of this declaration towards issues like biosphere, environment and development in general, entail problems since these issues have been and are addressed specifically in appropriate fora or international instruments, including legally binding ones, outside UNESCO, like ECOSOC, the MDG process, WIPO, CBD and other Multilateral Environment Agreements. With fullest respect for the high importance of these issues and without prejudging the question whether they as such are bioethical in nature or by any definition, it seems ineffective to try to duplicate or flank this work in other fora via the UNESCO Bioethics Declaration – indeed it even involves the risk of incompatibilities. Such an approach would also risk detracting from the standard setting role of the Declaration in a field which UNESCO has begun to occupy exclusively at the global level, therefore also detracting from UNESCO’s credibility as the global bioethics forum.</i></p> <p><i>We therefore suggest to focus clearly on medicine and the life sciences as applied to human beings. This does not exclude mentioning the links with environmental issues as in our new Article 1 on scope and in Article 15 of the Draft, because the mutual interdependence of the human kind and its future generations with the biosphere ethically implies human responsibility. Neither do we exclude mentioning links with “social responsibility” issues in Art. 13 such as with regard to health care where this link really exists.</i></p>
<p>UNITED KINGDOM</p>	<p><i>We support the development of this universal declaration on bioethics. In our view, the current draft has reached an acceptable compromise between differing views. We have however suggested some minor amendments for the purposes of clarification of a number of the Articles.</i></p>
<p>UNITED STATES OF AMERICA</p>	<p><i>Please note the amendments that we offered at the intergovernmental meeting in April, which are included in the Secretariat’s compilation of comments.</i></p> <p>Purpose: <i>The overarching purpose of this declaration should be to protect human life, human dignity, and human rights and fundamental freedom by promoting ethical behaviour in the fields of human health and human biology. The Declaration should provide guidance to Member States as they develop domestic policies and legislation in the field of bioethics, articulating a set of fundamental ethical principles to which all persons can aspire.</i></p>

	<p>Scope: <i>This Declaration should focus clearly on bioethical issues related to human biology and human health. While the United States recognizes the importance of environmental issues such as respect for the biosphere, the inclusion of these issues within its scope draws attention from the Declaration’s primary purpose--the protection of humans. Furthermore, environmental issues such as biodiversity conservation and benefits-sharing are already explicitly addressed under the Convention on Biological Diversity. Similarly, issues related to social and economic development are beyond its appropriate scope and in fact are already being addressed in other fora. In our view, the heart of the Declaration is captured in Articles 4-6, 8-12, and 21.</i></p> <p>Respect for Life: <i>The principal aim of this Declaration is to protect humans and to promote human dignity, human rights, and fundamental freedoms. The absence of appropriate references promoting respect for human life is glaring (i.e., in Articles 3, 4, 5, 7, and 8) and needs to be corrected in the text.</i></p> <p>Legal nature: <i>Declarations are non-binding instruments and therefore must use non-binding language. The Declaration cannot use language that implies a legal obligation, such as the term “shall.” Furthermore, it is inappropriate to refer to the “implementation” of, or restrictions on, the principles. This change must be reflected throughout the declaration.</i></p> <p>Targets: <i>UNESCO instruments are agreements among Member States, and, more specifically, UNESCO declarations are political agreements among such States. Consistent with this, the Declaration must be clearly addressed to States. It is inappropriate for a UNESCO Declaration to attempt to dictate the behaviour of individual actors. Use of the phrase “any decision or practice” (e.g., in Articles 1-13, 15-19) is problematic as it implicitly applies to individual actors, public or private institutions, and corporations, as well as to States.</i></p> <p>Non-duplication: <i>Great care needs to be taken not to undermine or duplicate existing international agreements, including but not limited to the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPS) and the Convention on Biological Diversity (CBD). Therefore, Articles 3, 13, 14, 15, 22, and 26, among others, must be amended.</i></p> <p>Education: <i>Capacity-building, awareness-raising, and education on bioethical issues are critical components of this declaration and should be given greater prominence in the text. This declaration should encourage States to foster open, pluralistic discussion and debate of bioethical issues and should encourage development of domestic practices that promote ethical treatment of humans and protection of human life, human dignity, and human rights.</i></p>
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TRANSVERSAL ISSUES

<p>GERMANY</p>	<p>1. On the issue of “shall” and “should” It is our view that the wording “shall” implies a legally binding instrument (which the declaration does not intend to be), whereas the wording “should” seems to be incommensurate with regard to human dignity and human rights. A solution to this problem could be to use the word “shall” where the Declaration refers to existing, applicable and binding international law; for other matters not regulated by international law, the word “should” will suffice. Germany proposes that the Secretariat check which principles are contained in which binding UN instruments (as referred to in the Preamble).</p> <p>2. On the issue of “any decision or practice” The repetitive introduction of every principle with the words “Any decision or practice” is undesirable. Such wording goes too far, since it encompasses basically any decision or practice of any individual researcher or doctor, of any private or public entity, of a company or a state. In our opinion, in order to make the declaration relevant at the practical level, it would suffice to name the addressees of the Declaration in the article about the scope and then clearly state the general principles. This would also help to duly highlight the principles themselves</p>
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INDONESIA	<p>1. On the issue of “shall” and “should” We support and accept the original reasoning of the IBC Drafting Group, as quoted from “Explanatory Memorandum on the Elaboration of the Preliminary Draft Declaration on Universal Norms on Bioethics” (SHS/EST/05/CONF.203/4 of 21 February 2005).</p> <p>(a) “shall” in “Principles”: Articles 4 to 15 lay out ethical principles that address policy makers, health care providers and different professional groups and bodies. Each of the principles provides guidelines for decisions and practices within the scope of the declaration, and therefore, in these articles the word “shall” is applied.</p> <p>(b) “should”, up to Member States to develop: In cases when the declaration contemplates that Member States will implement its principles, the word “should” is used;</p> <p>(c) “shall” in UNESCO’s commitment: When UNESCO itself is committed to the implementation and promotion of the declaration, the word “shall” is used, indicating a more binding engagement.</p> <p>2. Consecutive numbering of the chapters:</p> <ul style="list-style-type: none">A. General ProvisionsB. PrinciplesC. Conditions for implementationD. Implementation and promotion of the declarationE. Operation of the principles and declaration
MONACO	<p>1. On the issue of “shall” and “should” While maintaining both forms, a criterion should be established to justify the use of one rather than the other in specific provisions. For instance, the word “shall” would be reserved, with reference to earlier texts, for indisputable principles that are not to be reconsidered, such as those expressed in Article 4(a) and in Article 5.</p> <p>2. On the issue of “any decision or practice” The two terms should be retained. In fact, the principles identified in the declaration apply to both, which are relevant at different times. Even if the decision is satisfactory in terms of ethics, subsequent practice might not be.</p>

TITLE

Declaration on Universal Norms on Bioethics

Recommended title:

Universal Declaration on Bioethics and Human Rights

AUSTRALIA	M	Universal Declaration on Universal Norms on <u>Principles of</u> Bioethics
BOLIVIA		Universal Declaration on Bioethics and Human Rights
JAPAN	D	Universal Declaration on Bioethics and Human Rights
MONACO	C	<i>Human rights should be retained in the title. It is indeed what the declaration is about, namely, the protection of human rights in the face of scientific developments, in particular in biology. The declaration must not fall short of the Council of Europe's Oviedo Convention, which has human rights in its title.</i>
ROMANIA	M	Declaration on Universal Norms <u>General Guidelines</u> on Bioethics

PREAMBLE

AUSTRALIA	C	<i>While we agree in principle that a traditional preamble should be incorporated into the Declaration, we share other countries' concerns that the preamble is lengthy and unclear, therefore not helpful to the broader community, including the scientific community, to which the declaration is aimed.</i>
BOLIVIA	M	<p>The fifth and sixth paragraphs of the preamble should be moved to the beginning of the preamble as a general reference, as set out below. This amount of detail is needed not in the document itself but in a footnote reference.</p> <p><u>Recalling</u> the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration ...</p> <p><u>Also recalling</u> the two United Nations International Covenants on Economic ...</p> <p><u>Paragraphs: amended:</u></p> <p>“Stressing:</p> <ul style="list-style-type: none"> - (5) The validity of 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, - (6) The validity of the existing body of standards (**) and other international instruments in the field of human rights adopted by the United Nations and the specialized agencies of the United Nations system, national and international legislation and regulations in the field of bioethics, international and regional codes of conduct and guidelines and other texts in the field of science and technology,” <p><u>After “stressing”, move the second paragraph, set out below, to become the first “considering” paragraph of the preamble:</u></p> <p>2. <u>Conscious</u> of the unique capacity of human beings to reflect upon their own existence and on their environment; to perceive injustice; to avoid danger; to assume ...</p> <p>“Considers:</p> <p>(1) That the human being, recognized as the highest and most intelligent expression of our planet, has unavoidable responsibilities and duties to other forms of life.</p>

	<p>resisting actively and in a participatory manner damage done to nature and its biodiversity such as the indiscriminate hunting of animals, the plundering and deforestation of forests, desertification, environmental and water pollution and the alteration of ecosystems,”</p> <p><u>Move paragraph 8 to become the second “considering” paragraph of the preamble:</u></p> <p>(8) <u>Considering</u> that, by virtue of its Constitution, it is incumbent upon UNESCO to promote the democratic principles of the dignity, equality and respect of human beings and to reject any ...</p> <p>(2) “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 these constitute a sacred duty which all the nations must fulfil in a spirit of mutual assistance,”</p> <p><u>Alternative wording by Bolivia for the eleventh paragraph of the preamble:</u></p> <p>(11) <u>Recognizing</u> that scientific and technological developments have been, and can be ...</p> <p>(11) “That it is a remarkably positive fact that scientific and technological development has been of great benefit to humankind; recognizing, nevertheless, that such development must be regulated to secure enduring respect, as warranted, for the dignity and essence of individuals and their fundamental rights and freedoms and to achieve greater justice in the distribution of these benefits, having regard to the perception and knowledge of various ethnic groups, cultures and human societies in developing science and technology, which each one creates in the manner most appropriate to its own circumstances and without using technology as an instrument to create new forms of obligation, exploitation and dependency,”</p> <p><u>Alternative wording by Bolivia for the sixteenth paragraph of the preamble:</u></p> <p>(16) Stressing the need to reinforce international cooperation in the field of bioethics, taking into account in particular the special needs of developing countries,</p> <p>(16) “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 more vulnerable owing to conditions of underdevelopment and poverty,”</p> <p><u>New preambular paragraphs under “considering”:</u></p> <p>“That the purpose of bioethics is life, a supreme value to be defended, preserved and strengthened, respecting the quality and essence of the human species, in an existential context of interdependence with the biosphere and other living species, which must be respected on the basis of regulations that maintain a healthy ecological balance in the environment,”</p> <p>“That UNESCO’s task is to draw up standards and principles of universal scope, based on the shared values of humankind, in order to rise to the challenges inherent in scientific and technological development, taking into account the obligations and responsibilities of present generations to future generations,”</p> <p><u>New paragraphs at the end of the preamble:</u></p> <p>“THEREFORE:</p> <p>In the light of the above, DECLARES its full commitment to and support for bioethics principles and activities aimed at achieving the best conditions of life and habitability in the world on the basis of the following norms:”</p>
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<p>CANADA</p>	<p>A</p> <p>A</p> <p>M</p> <p>A</p> <p>C</p>	<p>...</p> <p><u>Bearing in mind</u> international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1989, 1993, 1996, 2000 and 2002 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences adopted in 1982 and amended in 1993 and 2002, <u>and the Montreal Declaration on Intellectual Disabilities of January 2005.</u></p> <p>...</p> <p><u>Recognizing</u> that bioethical issues may have an impact on individuals, families, groups or communities and humankind as a whole,</p> <p><u>NEW Further recognizing that unethical scientific and technological conduct has had particular impact on indigenous and local communities.</u></p> <p><u>Bearing in mind</u> that cultural diversity, as a source of exchange, innovation and creativity, is necessary for humankind and, in this sense, is the common heritage of humanity, but emphasizing that it may not be invoked to contravene fundamental human rights and <u>fundamental</u> freedoms,</p> <p>...</p> <p><u>Stressing</u> the need to reinforce international cooperation in the field of bioethics, taking into account in particular the special needs of developing countries, <u>indigenous peoples and vulnerable populations.</u></p> <p><i>Commentary: As currently drafted, there is a lack of consistency in the Declaration with respect to references to human dignity, human rights and fundamental freedoms. The following articles are relevant: Paragraphs 3, 11, 13 of the Preamble, articles 3, 4, 7, 8, 22 and 31. Canada suggests that a consistent approach be taken throughout the document, by using the phrase "human dignity, human rights and fundamental freedoms". In certain articles, Canada recommends that the reference to human dignity be removed. Canada's view is that human dignity is a positive value that can be respected and promoted. However, in relation to protecting against infringement, human rights and fundamental freedoms are the legal concepts that require protection.</i></p>
<p>GERMANY</p>	<p>M</p> <p>C</p>	<p>The General Conference,</p> <p><u>Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,</u></p> <p><u>Conscious</u> of the unique capacity of human beings to reflect upon their own existence and on their environment; to perceive injustice; to avoid danger; to assume responsibility; to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,</p> <p><u>Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,</u></p> <p><i>Recitals 1 and 3 belong together logically with 3 following 1 (1: rapid s+t developments, need for global response to ethical implications, 3: ethical issues raised by rapid advances in s+t ...). Recital 1 which contains the most general starting point (human capacity to reflect and express ethical principles) therefore should be switched with 2 in order to produce a more logical flow of thoughts.</i></p>

	A	<p><u>Recognizing</u> that ethical issues raised by the rapid advances in science and their technological applications should be examined <u>and resolved</u> with due <u>full and universal</u> respect to the inherent dignity of the human person and universal respect for, and of <u>to</u> observance of human rights and fundamental freedoms,</p> <p><u>Resolving</u> that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for the human species and for the biosphere,</p> <p><u>Recalling</u> the Universal Declaration of Human Rights of 10 December 1948,</p>
	M	<p><u>Also recalling 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 Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989,</u></p> <p><u>Recalling 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,</u> 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,</p>
	D	<p>Also recalling the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Recommendation of UNESCO on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),</p>
	C	<p><i>The present order of and within the 5th and 6th recitals of the Preamble which follows merely formal criteria seems inappropriate: for instance for instance</i></p> <ul style="list-style-type: none"><i>- important UN Conventions are mentioned in recital 6 after UNESCO Declarations under 5)</i><i>- CBD is mentioned between the Convention on Child's Rights and Rules on Persons with Disabilities</i> <p><i>The rearrangement: in our view should proceed from the general to the specific:</i></p>

	<p>A</p> <p>D</p> <p>A</p> <p>C</p> <p>A</p> <p>D</p>	<p><i>fundamental UN human rights instruments should be separately mentioned first, starting with the Universal Declaration of Human Rights, followed by the various UN human rights conventions. A separate subsequent section should contain references to the more specific UNESCO instruments (e.g. on Human Genome and Human Rights and on Human Genetic Data) with those relating to human beings listed first, followed by those of other UN organizations (e.g. FAO), and then (7th recital) regional organizations (e.g. Council of Europe) and NGOs (Declaration of Helsinki). The order of these various references should be changed accordingly. It should also be considered whether the instruments unrelated to human beings should be separated from those referring to humans and be grouped in a separate recital, which would improve readability and understanding.</i></p> <p><u>Bearing in mind</u> international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, together with its additional protocols, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1989, 1993, 1996, 2000 and 2002 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences adopted in 1982 and amended in 1993 and 2002,</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 respect of human beings and to reject any doctrine of inequality, and that this constitutes a duty which all nations must fulfil in a spirit of mutual assistance,</p> <p><u>Considering also</u> UNESCO's role in developing universal principles based on shared ethical values to guide scientific and technological development and social transformation, in order to identify emerging challenges in science and technology taking into account the responsibility of the present generation towards future generations, and that questions of bioethics, which necessarily have an international dimension, be treated as whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, and taking account not only of the current scientific context but also of future developments,</p> <p><u>Aware</u> that human beings are an integral part of the biosphere and that they have responsibilities and duties towards each other as well as/but also to animals and towards other forms of life,</p> <p><i>As regards humanity's responsibilities and duties for the biosphere and other forms of life, which the Declaration refers to in several places, Germany is in favour of adding a specific reference to the protection of animals. Such formulations could be included in the Preamble recital 10 (and also in the Operative Part in Articles 3 and 15).</i></p> <p><u>Recognizing</u> that, based on the freedom of science and research as a necessary condition, scientific and technological developments have been, and can be, of great benefit to humankind in increasing <i>inter alia</i> life expectancy and improving quality of life and <u>emphasizing</u> that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the inherent dignity of the human person and the universal respect for, and observance of, human rights and fundamental freedoms,</p> <p>...</p>
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	D	<p>Considering the need for a new approach to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity and to the interest of humanity,</p> <p>...</p>
INDONESIA	D	<p><i>The General Conference,</i></p> <p>...</p> <p>Also recalling the two United Nations International Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the United Nations General Assembly in 1993, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Recommendation of UNESCO on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the Trade Related Aspects of Intellectual Property Rights Agreements (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPs Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),</p> <p>Bearing in mind international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1989, 1993, 1996, 2000 and 2002 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences adopted in 1982 and amended in 1993 and 2002,</p> <p>Considering that, by virtue of its Constitution, it is incumbent upon UNESCO to promote the democratic principles of the dignity, equality and respect of human beings and to reject any doctrine of inequality, and that this constitutes a duty which all nations must fulfil in a spirit of mutual assistance;</p> <p>Considering also UNESCO's role in developing universal principles based on shared ethical values to guide scientific and technological development and social transformation, in order to identify emerging challenges in science and technology taking into account the responsibility of the present generation towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data, and taking account not only of the current scientific context but also of future developments;</p> <p>...</p> <p>Considering the need for a new approach to social responsibility to ensure, whenever possible, that progress in science and technology contributes to justice, equity and to the interest of humanity;</p> <p>Stressing the need to reinforce international cooperation in the field of bioethics,</p>

	C	taking into account in particular the special needs of developing countries, Proclaims the principles that follow and adopts the present Declaration. <i>We recommend that we go “back to basics”, and simplify the “preamble” part, ensuring that the “strength” of the declaration should be in this part, so that it becomes “clear” and “obvious” to all, as with the Universal Declaration on Human Rights of 1948.</i>
ROMANIA	A	<u>Bearing in mind</u> international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, adopted in 1997 and entered into force in 1999, and their additional protocols as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1989, 1993, 1996, 2000 and 2002 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences adopted in 1982 and amended in 1993 and 2002,

GENERAL PROVISIONS

Article 1 – Use of Terms

For the purpose of this Declaration:

- (i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;
- (ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and
- (iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.

Article 2 – Scope

The principles set out in this Declaration apply as appropriate and relevant:

- (i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and
- (ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.

ARGENTINA	I*	M	<u>Article 2 – Scope</u> (ii) to those who make such decisions or carry out such practices, whether they are primarily the States, but also corporations, public or private institutions, professional groups or individuals.
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* In the following tables (Articles 1 to 10):

(I): refers to written, and as far as possible, oral amendments proposed during the first session of the intergovernmental meeting of experts (Paris 4-6 April 2005);

(II): refers to proposed written amendments received from Member States as of 3 June 2005 with a view to the second session of the intergovernmental meeting of experts aimed at finalizing a draft declaration (Paris, 20-24 June 2005).

AUSTRALIA	II	C	<i>Waits for the results of the intersessional consultations.</i>
BELGIUM	II	M	<p><u>Article 1 – Use of terms</u></p> <p>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of debates concerning conflicts of values in ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;</p>
BURKINA FASO	I	M	<p><u>Article 1 – Use of terms</u></p> <p>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications ethics applied to the fields of the health, life and social sciences;</p> <p>C <i>As understood by Aristotle, ethics is applied to such fields as politics, relations between individuals, professional activities, and so on. As far as we are concerned, the idea here is to apply ethics to the fields of the health, natural and social sciences.</i></p>
CYPRUS	II	D	<p><u>Article 1 – Use of Terms</u></p> <p>For the purpose of this Declaration:</p> <p>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;</p> <p>(ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and</p> <p>(iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.</p> <p>M <u>Article 2 – Scope</u></p> <p>The principles set out in this Declaration apply as appropriate and relevant:</p> <p>(i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and</p> <p>(ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.</p> <p><u>1. (a) This Declaration sets out principles that will be applied to bioethical issues, questions and dilemmas arising from the development and application, by States, of medical, life and social sciences and the technologies associated with them;</u></p> <p><u>(b) These principles should be the guidance for any other person involved in the activities referred to in paragraph (a).</u></p> <p><u>2. The principles set out in this Declaration aim at protecting and promoting human dignity, human rights and fundamental freedoms and the biosphere.</u></p>

FINLAND	I	M	<p><u>Article 1 – Use of Terms</u></p> <p>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution application/ discussion;</p>
GERMANY	II	D	<p>Article 1 – Use of Terms For the purpose of this Declaration: (i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications; (ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and (iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.</p> <p>Article 2 1 – Scope</p> <p>The principles set out in this Declaration apply as appropriate and relevant:</p> <p>(i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and <u>The principles set out in this Declaration apply to ethical issues raised by medicine and life sciences as applied to human beings while recognizing that they have responsibilities towards other forms of life in the biosphere.</u></p> <p>(ii) The Declaration is addressed to States. As appropriate and relevant, it also provides guidance to those who make such decisions or carry out such practices, whether they are of individuals, professional groups, public or private institutions, and corporations, public and private or States.</p> <p><i>The detailed definitions in Art. 1 containing elements which are problematic, redundant or tautological are superfluous. In Germany’s view it is both necessary and possible to simplify and amalgamate the provisions on use of terms (Article 1) and scope (Article 2). On the basis of our proposed wording on scope, Article 1 can be deleted. Art. 2 Para. (i) would be partly retained and amended.</i></p> <p><i>As regards humanity’s responsibility for the biosphere, Germany is in favour of a specific reference to the protection of animals. Such formulations could be included in the Preamble recital 12 and also in the Operative Part in Articles 3 (vi) and 15 specifically mention animals.</i></p>
INDIA	I	M	<p><u>Article 1 – Use of Terms</u></p> <p>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere <u>moral, legal and social dimensions of the applications of knowledge in biomedical and social sciences, and the technologies associated with them; primarily aimed at protecting and promoting human dignity, human rights and fundamental freedoms;</u> including issues related to <u>equitable</u> availability and accessibility of scientific and technological developments;</p> <p>(ii) the term “bioethical issues” refers to the issues <u>arising out of</u> Article 1(i); and</p>

			<p>(iii) the term “decision or practice” refers to a decision or practice made or carried out within the scope of this Declaration and involving bioethical issues.</p> <p><u>Article 2 – Scope</u></p> <p>(ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States, public or private.</p>
INDONESIA	II	M	<p><u>Article 1 – Use of Terms</u></p> <p>For the purpose of this Declaration:</p> <p>(i) <u>in its first sense</u>, the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, life sciences and social sciences biotechnology, as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications. <u>The term also refers to any issues concerning the respect owed to human life and ethical issues linked to the availability and full accessibility to humanity as a whole of advances in science and technology. Lastly, by extension, the term “bioethics” lastly refers to issues raised by animal life and the biosphere.</u></p> <p>(ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and</p> <p>(iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.</p> <p><u>Article 2 – Scope</u></p> <p>(a) The principles set out in this Declaration apply as appropriate and relevant:</p> <p>(i) to decisions or practices made or carried out in the <u>application field</u> of medicine, life and social sciences and biotechnological research and their effect on individuals, families, groups and human society as a whole; communities; and</p> <p>(ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.</p> <p><u>(b) they are intended for governments and legislators, professional groups and civil society.</u></p>
JAPAN	II	C	<p><i>Waits for the results of the intersessional consultations.</i></p>
LUXEMBURG	II	c	<p><i>Waits for the results of the intersessional consultations.</i></p>
PORTUGAL	I	D	<p><u>Article 1 – Use of Terms</u></p> <p>(ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and</p> <p>(iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.</p>
		A	<p><u>Article 2 – Scope</u></p> <p>(i) to decisions or practices made or carried out in the application of medicine, life and social sciences <u>as far as restricted to research and purposes of assistance</u> to individuals, families, groups and communities; and</p>
		C	<p><i>If (ii) and (iii) of Article 1 are deleted, the title “use of terms” has to be changed because the only term will be “bioethics”. The definition of</i></p>

			<p><i>“bioethics”, broad as it is, could/should enhance the idea that addresses are specially to human beings.</i></p>
ROMANIA	II	A	<p><u>Article 1 – Use of Terms</u></p> <p>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary study and resolution of ethical issues raised by medicine, biotechnology, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;</p> <p><u>Article 2 – Scope</u></p> <p>...</p> <p>(ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, communities, public or private institutions, corporations or States.</p>
RUSSIAN FEDERATION	II	M	<p>(i) the term “bioethics” refers to the systematic, pluralistic and interdisciplinary discussion, study and resolution of ethical, legal and social issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;</p>
		C	<p><i>The word “systematic” seems unnecessary and redundant. One of the most striking traits of bioethics is that it represents first of all a field of sharp discussions. As for addition of “legal and social”, we have in mind real scope of interest of bioethics which goes far beyond ethical issues per se and touch rather essentially legal and social issues as well. See for example art. 20 i); art. 23 b), etc.</i></p>
SYRIA	I	M	<p><u>Article 1 – Use of Terms</u></p> <p>(i) the term “bioethics” refers to For the purposes of this Declaration, bioethics is defined as the field of systematic, pluralistic and interdisciplinary study and resolution of ethical that aims to resolve issues raised by medicine, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;</p> <p>(ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and</p> <p>(iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.</p>
TURKEY	I	M	<p><u>Article 2 – Scope</u></p> <p>The principles set out in this Declaration apply as appropriate and relevant.</p> <p>(i) ...</p> <p>(ii) as appropriate and relevant, to those who make such decisions or carry out such practices,...</p>
UNITED KINGDOM	II	C	<p><i>Waits for the results of the intersessional consultations.</i></p>

<p>UNITED STATES OF AMERICA</p>	<p>II</p>	<p>M</p>	<p><u>Article 1 – Use of Terms</u></p> <p>For the purpose of this Declaration, (i) the term “bioethics” refers to <u>those ethical issues arising from the application of science and technology in raised by medicine and scientific research relating to human biology and human health, life and social sciences as applied to human beings and their relationship with the biosphere, including issues related to the availability and accessibility of scientific and technological developments and their applications;</u></p> <p>(ii) the term “bioethical issues” refers to the issues mentioned in Article 1(i); and</p> <p>(iii) the term “decision or practice” refers to a decision or practice arising within the scope of this Declaration and involving bioethical issues.</p> <p><u>Article 2 - Scope</u></p> <p>The principles set out in this Declaration <u>should</u> apply as appropriate and relevant:</p> <p><u>(i) help guide States in the formulation of their domestic legislation and policies on issues of bioethics; and</u></p> <p><u>(ii) protect human beings while recognizing the importance of the biosphere.</u></p> <p>(i) to decisions or practices made or carried out in the application of medicine, life and social sciences to individuals, families, groups and communities; and</p> <p>(ii) to those who make such decisions or carry out such practices, whether they are individuals, professional groups, public or private institutions, corporations or States.</p>
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Article 3 – Aims

The aims of this Declaration are:

- (i) to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned;
- (ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law;
- (iii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;
- (iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, policy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;
- (v) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
- (vi) to recognize the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and
- (vii) to safeguard and promote the interests of the present and future generations.

ARGENTINA	I	D	(v) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
BELGIUM	II	C A M M	<p>(i) <i>the current paragraph is acceptable.</i></p> <p><u>NEW (ii) to provide a universal framework of fundamental principles for the development of further international instruments that address bioethical issues, and for the interpretation and application, as required, of the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data; (as proposed by Canada (II))</u></p> <p>(ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law <u>the human rights guaranteed by international law</u>;</p> <p>...</p> <p>(iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, policy makers, non governmental organizations, representatives of civil society, the persons concerned and society as a whole <u>other interested persons, individuals, professional groups, public or private institutions and corporations</u>;</p> <p><i>OR</i></p> <p>(iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious, and professional <u>and non-denominational</u> groups concerned, policy-makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;</p>
BOLIVIA	II	A	<p>...</p> <p><u>(viii) to ensure that all human beings enjoy decent living conditions that provide adequate nutrition, health, housing, education, individual and collective well-being, without disrupting the natural environment and ecological balance;</u></p> <p><u>(ix) to promote justice, liberty, peace and solidarity for all human beings as shared purpose in each and every country and the world as a whole;</u></p> <p><u>(x) to develop a level of collective awareness that encourages, prepares and mobilizes society for the defence of life, against all conditions that suppresses, affects or harms it.</u></p>
CANADA	II	M A	<p>(i) to provide a universal framework of fundamental principles and procedures to <u>help</u> guide States in the formulation <u>and implementation</u> of their legislation and policies in the field of bioethics, and <u>(ii) to form the basis for guidelines concerning bioethical issues for the individuals, communities, groups and institutions and corporations, public and private concerned;</u></p> <p><u>(iii) to provide a universal framework of fundamental principles for the development of further international instruments that address bioethical issues, and for the interpretation and application, as</u></p>

		<p>M</p> <p>M</p> <p>C</p>	<p><u>required, of the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data:</u></p> <p>(ii) (iv) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with <u>the</u>; international <u>law of</u> human rights law;</p> <p>(iii) (v) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;</p> <p>(iv) (vi) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, policy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole <u>government, individuals, professionals, groups, communities, institutions and corporations, public and private</u></p> <p>(v) (vii) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;</p> <p>(vi) (viii) to recognize the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and</p> <p>(vii) (ix) to safeguard and promote the interests of the present and future generations.</p> <p><i>Commentary: In general, Canada supports the provisions of Article 3 and its articulation of the aims of the Declaration. Canada suggests some specific drafting changes noted above, the most important of which is providing a specific statement of aims pertaining to States that is separate from that pertaining to other persons. The proposed Declaration is, first and foremost, a declaration of States, and this should be reflected quite clearly in the document.</i></p> <p><i>A particular point Canada would like to draw attention to is that as currently drafted, there is a lack of consistency between the lists of interested parties used throughout the Declaration. The following provisions contain various lists of interested parties: paragraphs 11 and 12 of the Preamble, and articles 2, 3, 8, 17, 19, 21, 23, and 26. Canada recommends using a consistent phrase, such as “individuals, groups, institutions and corporations, public and private” or a similar phrase, where appropriate.</i></p>
<p>GERMANY</p>	<p>II</p>	<p>M</p> <p>M</p>	<p>(ii) to promote respect for <u>and protection of</u> human dignity, and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law;</p> <p>(iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, policy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole <u>all stakeholders</u>;</p>

		M	(v) to promote equitable appropriate access to medical, scientific and technological developments <u>in the field of medicine and life sciences</u> as well as the greatest possible flow and the rapid appropriate sharing of knowledge concerning those developments and the <u>fair and equitable</u> sharing of benefits, with particular attention to the needs of developing countries;
		A	(vi) to recognize the importance of biodiversity and the responsibilities of human beings towards <u>animals and</u> other forms of life in the biosphere; and
INDIA	I	M	(i) to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies <u>or other instruments</u> in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned <u>as well as to individuals and communities to guide their behaviour and actions;</u>
		D	(ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law; (iii) (ii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;
		M	(iv) (iii) to foster multidisciplinary and pluralistic dialogue about bioethical issues between <u>all stakeholders including</u> scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned; <u>involved in</u> policy makers, <u>making and implementation</u> and society as a whole;
		M	(v) (iv) to promote equitable access to medical, scientific <u>knowledge</u> and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
		M	(vi) (v) to recognize <u>promote</u> the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and (vii) (vi) to safeguard and promote the interests of the present and future generations.
INDONESIA	II	M	(i) to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies <u>or other instruments</u> in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned <u>as well as to individuals and communities to guide their behaviour and actions;</u> <i>(as proposed by India (I))</i>
		D	(ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law; <i>(as proposed by India (I))</i>

			<p>(iii) (ii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms; <i>(as proposed by India (I))</i></p> <p>M (iv) (iii) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders including scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned; involved in policy makers, non-governmental organizations, representatives of civil society, the persons concerned making and implementation and society as a whole; <i>(as proposed by India (I))</i></p> <p>M (v) (iv) to promote equitable access to medical, scientific knowledge and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries; <i>(as proposed by India (I))</i></p> <p>M (vi) (v) to recognize promote the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and <i>(as proposed by India (I))</i></p> <p>(vii) (vi) to safeguard and promote the interests of the present and future generations. <i>(as proposed by India (I))</i></p>
MEXICO	I	A	(iii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, whilst ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms and enhance social transformation;
ROMANIA	II	A	(ii) to promote respect for human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law and cultural diversity when that does not contradict human rights law;
		C	<i>In some cases, customs are more severe than human rights law, more protective for human beings and environment and it might be useful to admit their prevalence. Abuses are limited by Article 5 and also by the formulation proposed above in itself.</i>
		A	(vii) to safeguard and promote the interests of the present and future human generations.
RUSSIAN FEDERATION	II	M	(i) to provide a universal framework of fundamental principles and procedures to guide States in addressing bioethical issues which arise in the formulation of their legislation and policies in the field of bioethics, and in the delivery of their services and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned;
		A	<u>NEW (ii) to provide a universal framework of fundamental principles for the development of further international instruments that address bioethical issues, and for the interpretation and application, as required, of the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data;</u> <i>(as proposed by Canada (II))</i>

		D	(iii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms; <i>(as proposed by the United States of America (II))</i>
		M	(v) to promote equitable access to medical, scientific knowledge and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries; <i>(as proposed by Argentina (I) and India (I))</i>
		A	(vi) to recognize the importance of biodiversity and the responsibilities of human beings towards animals and other forms of life in the biosphere; and <i>(as proposed by Germany (II))</i>
		A	(vii) to help safeguard and promote the interests of the present and future generations. <i>(as proposed by the United States of America (II))</i>
SAUDI ARABIA	I	D	(v) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
TURKEY	I	M	(iv) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians, lawyers and all the other intellectual, religious and professional groups concerned, policy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;
UNITED STATES OF AMERICA	II	D	(i) to provide a universal framework of fundamental principles and procedures to guide States in the formulation of their legislation and policies in the field of bioethics, and to form the basis for guidelines concerning bioethical issues for the individuals, groups and institutions concerned;
		M	(ii) (i) to promote respect for human life, human dignity and the protection and promotion of human rights and fundamental freedoms in any decision or practice involving bioethical issues, in accordance with international human rights law;
		D	(iii) (ii) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while ensuring that such developments occur within the framework of ethical principles that respect human dignity and protect human rights and fundamental freedoms;
		D	(iv) (iii) to foster multidisciplinary and pluralistic dialogue about bioethical issues between scientists, health professionals, lawyers, philosophers, ethicists, theologians and all the other intellectual, religious and professional groups concerned, policy makers, non-governmental organizations, representatives of civil society, the persons concerned and society as a whole;
		M	(v) (iv) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries; to promote attention to, consistency in, and best practices in bioethical issues

			<u>involved in the conduct of human research and treatment; and to encourage the exchange of scientific information with particular attention to the needs of developing countries;</u>
		D	(vii) (v) to recognize the importance of biodiversity and the responsibilities of human beings towards other forms of life in the biosphere; and
		A	(vii) (vi) to help safeguard and promote the interests of the present and future generations.

PRINCIPLES

PORTUGAL	I	C	<p><i>Revise the ordering of articles from individual-centres issues to a progressively broader scope (society and nature):</i></p> <p><i>Article 4 – Human Dignity and Human Rights</i> <i>Article 6 – Benefit and Harm</i> <i>Article 9 – Autonomy and Individual Responsibility</i> <i>Article 10 – Informed Consent</i> <i>Article 11 - Privacy and Confidentiality</i> <i>Article 5 – Equality, Justice and Equity</i> <i>Article 8 – Non-Discrimination and Non-Stigmatization</i> <i>Article 7 – Respect for Cultural Diversity and Pluralism</i> <i>Article 12 – Solidarity and Cooperation</i> <i>Article 13 – Social Responsibility</i> <i>Article 14 – Sharing of Benefits</i> <i>Article 15 – Responsibility towards the Biosphere</i></p>
RUSSIAN FEDERATION	II	C	<p><i>We think that present draft of the declaration contains too many principles (12). The more principles the declaration will contain, the more possibilities will be for conflicts between the principles and, correspondingly, for difficulties in application of these principles, as is foreseen in art. 29. It seems, in particular, that principles of Art. 5 and 14 can be combined into one principle. The same can be said about Art. 9 and 10.</i></p>

Article 4 – Human Dignity and Human Rights

- (a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms;
- (b) Any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society.

AUSTRALIA	II	M	<p>b) Any decision or practice shall respect the principle that the interests and welfare of the human person individual prevail over the sole should have priority over the rights and interests <u>interests</u> of science or society.</p>
		C	<p><i>Australia considers there is merit in following the approach used in the International Declaration on Human Genetic Data to achieve an appropriate balance in the text vis-à-vis the rights of the individual and the society i.e.</i></p>

BELGIUM	II	M	<p>a) Any decision or practice shall be made or carried out with full respect for the inherent Human dignity of the human person, human rights and fundamental freedoms shall be fully respected;</p> <p>b) Any decision or practice shall respect the principle that ¶ The interests and welfare of the human person being shall prevail over the sole interest of science or society.</p> <p><i>The three terms “human dignity, human rights and fundamental freedoms” must remain inseparable.</i></p> <p>C <i>The term “human being” is preferable to “human person” and “individual”.</i></p>
BOLIVIA	II	M	<p>Article 4 – Human Dignity and Human Rights Primacy of the Human Being</p> <p>a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person being, human rights and fundamental freedoms;</p> <p>b) Any decision or practice shall respect the principle that the interests and welfare of the human person being prevail over the sole interest of science or society.</p>
CANADA	II	M	<p>a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person human dignity, human rights and fundamental freedoms;</p>
COSTA RICA	I	A	<p>a) Any decision or practice shall be made or carried out with full respect for human life, the inherent dignity of the human person, human rights and fundamental freedoms;</p>
GERMANY	II	M	<p>a) Any decision or practice shall be made or carried out with full respect for ¶ The inherent dignity of the human person, human rights and fundamental freedoms shall be respected;</p> <p>b) Any decision or practice shall respect the principle that ¶ The interests and welfare of the human person should prevail over the sole interest of science or society.</p>
INDONESIA	II	D	<p>b) Any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society.</p>
JAPAN	II	M	<p>a) Any decision or practice shall should be made or carried out with full respect for the inherent dignity of the human person, human rights and fundamental freedoms;</p> <p>b) Any decision or practice shall should respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society.</p>
KENYA	I	M	<p>a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person being, human rights and fundamental freedoms;</p> <p>b) Any decision or practice shall respect the principle that the interests and welfare of the human person being prevail over the sole interest of science or society.</p>

LUXEMBOURG	I	M	b) Any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society. <u>The interests and welfare of the individual shall in all circumstances prevail over the sole interest of science. A judicious balance shall be struck between the interests and welfare of the individual and the interests of society.</u>
ROMANIA	II	A	b) Any decision or practice shall respect the principle that the interests and welfare of the human person prevail over the sole interest of science or society. <u>A judicious balance shall be struck between the interests and welfare of the individual and the interests of society.</u>
RUSSIAN FEDERATION	II	M	a) Any decision or practice shall be made or carried out with full respect for the inherent dignity of the human person being , human rights and fundamental freedoms; <i>(as proposed by Bolivia (II) and Kenya (I))</i>
SAUDI ARABIA	I	M	b) Any decision or practice shall respect the principle that <u>The interests and welfare of the human person shall prevail over the sole interest of science or society.</u>
UNITED KINGDOM	II	M	b) Any decision or practice shall respect the principle that the interests and welfare <u>the fundamental rights and freedoms</u> of the human person. <u>These should</u> prevail over the sole interests of science or society.

Article 5 – Equality, Justice and Equity

Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably.

BELGIUM	II	M	Any decision or practice shall respect <u>The fundamental equality of all human beings in dignity and rights shall be respected, and ensure that they are treated justly and equitably.</u>
		C	<i>Although it could be argued that Article 5 is rendered meaningless by Articles 7 (Respect for Cultural Diversity and Pluralism) and 8 (Non-Discrimination and Non-Stigmatization), Belgium would like the article to be retained, possibly brought closer into line with Articles 7 and 8 and, if necessary, worded inversely (see proposal).</i>
BRAZIL	I		a) Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably.
		A	<u>b) Their should be no double standard concerning the rights to health and access to essential medicine of the populations of both developed and developing countries.</u>
GERMANY	II	D	Any decision or practice shall respect <u>The fundamental equality of all human beings in dignity and rights shall be respected and it shall be ensured</u> that they are treated justly and equitably.
INDIA	I	M	Any decision or practice shall respect <u>The fundamental equality of all human beings in dignity and rights shall be respected and it shall be ensured</u> that they are treated justly and equitably.
INDONESIA	II	M	Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and <u>it shall be ensured</u> that they are treated justly and equitably.

JAPAN	II	M	Any decision or practice shall should respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably.
ROMANIA	II	M	Any decision or practice shall The applications of the results of medical research, life sciences, biotechnology and also social regulations shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably.
RUSSIAN FEDERATION	II	M	Any decision or practice shall respect The fundamental equality of all human beings in dignity and rights should be respected and ensure that they are treated justly and equitably their just and equitable treatment should be promoted. <i>(as proposed by the United States of America (II))</i>
SAUDI ARABIA	I	M	Any decision or practice shall respect the fundamental equality of all human beings in dignity and rights and ensure that they are treated justly and equitably. a) The fundamental equality of all human beings in dignity and rights should be respected, it should be ensured that they are treated justly and equitably. b) There should be no differential treatment concerning the rights to health and access to essential medicine of the populations of both developed and developing countries.
UNITED STATES OF AMERICA	II	M	Any decision or practice shall respect The fundamental equality of all human beings in dignity and rights should be respected and ensure that they are treated justly and equitably their just and equitable treatment should be promoted.

Article 6 – Benefit and Harm

Any decision or practice shall seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice.

AUSTRALIA	II	M	Any decision or practice shall seek to benefit the person individual or individuals / person or people concerned and to minimize the possible harm resulting from that decision or practice.
		C	<i>While the declaration is seeking to protect the individual person, there may well be instances where decisions or practices (e.g. research) are aimed at particular ethnic or community groups.</i>
BELGIUM	II	A	Any decision or practice shall seek to benefit directly or indirectly the person concerned and to minimize the possible harm resulting from that decision or practice.
BOLIVIA	II	A	Any decision or practice shall seek to maximize the benefit the persons concerned and to minimize the possible harm resulting from that decision or practice

GERMANY	II	M	Any decision or practice shall <u>should</u> seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice. <u>The application of medicine and life sciences</u>
		A	<u>NEW Article 6 bis – Responsibility for Future Generations</u> <u>The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.</u>
INDIA	I	A	Any decision or practice shall seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice. <u>The benefit may be direct or indirect through advancement of knowledge and is intended to benefit humanity in general.</u>
INDONESIA	II	A	Any decision or practice shall seek to benefit <u>directly or indirectly</u> the person concerned and to minimize the possible harm resulting from that decision or practice.
JAPAN	II	M	Any decision or practice shall <u>should</u> seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice.
RUSSIAN FEDERATION	II	M	Any decision or practice shall <u>should</u> seek to benefit the person <u>or persons</u> concerned and to minimize the possible harm resulting from that decision or practice. <i>(As to the first part of the sentence, as proposed by Germany (II))</i>
UNITED KINGDOM	II	M	Any decision or practice shall seek to benefit the person concerned and to minimize the possible harm resulting from that decision or practice <u>or benefit other people in the same situation or with the same condition now or in the future. Any decision or practice should also seek to minimize any resulting harms.</u>

Article 7 – Respect for Cultural Diversity and Pluralism

Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.

ARGENTINA	I	D	Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, <u>Such</u> considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.
AUSTRALIA	II	M	Any decision or practice shall <u>should</u> take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and or spiritual beliefs and <u>or any</u> other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.

BELGIUM	II	M	<p>Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. The importance of cultural diversity and pluralism shall be given due regard. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p> <p><i>(as proposed by India (I) for the first part of the Article)</i></p>
CANADA	II	M	<p>Any decision or practice shall take into account the cultural backgrounds, schools of thought, world views, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p>
GERMANY	II	M	<p>Any decision or practice shall take into account the Cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society should be given due regard. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p>
		C	<p><i>Article 7 is not properly placed between articles containing individual human rights and should be shifted after 11. In general, Germany would support the Portuguese proposal for realigning the articles in this section.</i></p>
INDIA	I	M	<p>Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. The importance of cultural diversity and pluralism should be given due regard. However, such considerations shall should not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p>
INDONESIA	II	D	<p>Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p> <p><i>(as proposed by Saudi Arabia (I))</i></p>
JAPAN	II	M	<p>Any decision or practice shall should take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall should not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p>
ROMANIA	II	M	<p>Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and philosophical convictions and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms and the physical integrity and biological future of forthcoming generations nor upon the principles set out in this Declaration, nor to limit their scope.</p>
		A	

RUSSIAN FEDERATION	II	M	<p>Any decision or practice shall take into account the <u>Cultural</u> backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society <u>should be given due regard</u>. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p> <p><i>(as proposed by Germany (II))</i></p>
SAUDI ARABIA	I	D	<p>Any decision or practice shall take into account the cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p>
UNITED STATES OF AMERICA	II	M	<p>Any decision or practice shall <u>should</u> take into account the <u>importance of</u> cultural backgrounds, schools of thought, value systems, traditions, religious and spiritual beliefs and other relevant features of society <u>diversity and pluralism</u>. However, such considerations shall <u>should</u> not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope.</p>

Article 8 – Non-Discrimination and Non-Stigmatization

In any decision or practice, no one shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.

BELGIUM	II	D	<p>In any decision or practice, <u>No one shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.</u></p>
BOLIVIA	II	A M	<p>In any decision or practice, no one shall be subjected to discrimination based on any grounds, <u>including physical, mental or social conditions, diseases or genetic characteristics</u>, intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual <u>human being</u>, nor shall such grounds be used to stigmatize an individual, a family, a group or a community</p>
BRAZIL	I	M A	<p>In any decision or practice, no one <u>No person, family, group or community</u> shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, <u>a family, a group or a community</u>, nor shall such grounds be used to stigmatize an individual, a family, a group or a community</p>
CANADA	II	M A	<p>(a) In any decision or practice <u>[In the resolution of bioethical issues]</u>, no one shall be subjected to discrimination based on any grounds <u>that are</u> intended to infringe, or having <u>have</u> the effect of infringing the human dignity, human rights or <u>and</u> fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.</p> <p>(b) <u>[In any decision or practice], every effort should be made to ensure that any such grounds are not used to stigmatize an individual, a group or a community.</u></p>

GERMANY	II	D	In any decision or practice, No one shall be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community.
INDONESIA	II	M	In any decision or practice, no one shall No individual, group or race should be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, group or race , nor shall such grounds be used to stigmatize an individual, a family, a group or a community or race . (as proposed by Saudi Arabia (I))
JAPAN	II	M	In any decision or practice, no one shall should be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall should such grounds be used to stigmatize an individual, a family, a group or a community.
MEXICO	I	A	In any decision or practice, no one shall be subjected to discrimination based on any grounds, including gender, age, ethnicity, disability , intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall such grounds be used to stigmatize an individual, a family, a group or a community. Furthermore, any decision or practice should not be made taking advantage or ignoring the discriminatory and stigmatisation conditions already in place.
RUSSIAN FEDERATION	II	M	In any decision or practice, No one shall should be subjected to discrimination based on any grounds in a way that is intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall should such grounds be used to stigmatize an individual, a family, a group or a community. (as proposed by the United States of America (II))
SAUDI ARABIA	I	M	In any decision or practice, no one shall No individual, group or race should be subjected to discrimination based on any grounds intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, group or race , nor shall such grounds be used to stigmatize an individual, a family, a group or a community or race .
UNITED STATES OF AMERICA	II	M	In any decision or practice, no one shall should be subjected to discrimination based on any grounds in a way that is intended to infringe, or having the effect of infringing, the human dignity, human rights or fundamental freedoms of an individual, nor shall should such grounds be used to stigmatize an individual, a family, a group or a community.

Article 9 – Autonomy and Individual Responsibility

Any decision or practice shall respect the autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others.

BELGIUM	II	C	<i>The current wording is acceptable.</i>
GERMANY	II	M	Any decision or practice shall respect The autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others should be respected .

JAPAN	II	M	Any decision or practice shall should respect the autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others.
RUSSIAN FEDERATION	II	C	<i>We think that there is some ambiguity in the formulation of Article 9, as it can be perceived as opening up the possibility for autonomous choice for persons to take or not to take responsibility for their decisions.</i>
UGANDA	I	A	Any decision or practice shall respect the autonomy and capacity of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others.
UNITED STATES OF AMERICA	II	M	Any decision or practice shall respect The autonomy of persons to make decisions and to take responsibility for those decisions while respecting the autonomy of others should be respected .

Article 10 – Informed Consent

- a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.
- b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.
- c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration.

ARGENTINA	I	A	a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, without inducement , informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.
		A	NEW d) Special consideration and care will be take to have consent for vulnerable persons by ethnic, social, cultural or other conditions.
AUSTRALIA	II	M	c) In any decision or practice in the fields of [scientific] research and medical treatment involving persons who do not have the capacity to incapable of giving informed consent, special protection shall be given should be provided to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration. by obtaining consent in accordance with domestic law and consistent with international human rights law, having regard to the best interests of the persons concerned.
		C	<i>This article is problematic and we have particular difficulty with the ambiguity regarding the description of consent, the problem with describing consent differently in each paragraph is:</i> <ul style="list-style-type: none"> a) that research and treatment may sometimes be intertwined; b) there seems to be a lesser standard of consent for medical treatment; c) that treatment of people who do not have the capacity to consent, is ambiguous about whether it applies to consent to research or consent to treatment or both.

BELGIUM	II	A	<p>a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned, <u>based on appropriate information</u>. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.</p>
		C	<p><i>The current wording is acceptable.</i></p>
		A	<p><u>NEW (d) Limitations on the principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international human rights law.</u></p> <p><i>(taken from Article 8 of the International Declaration on Human Genetic Data)</i></p>
BURKINA FASO	I	A	<p>COLLECTIVE AGREEMENT <u>In case of research carried out on a group of persons or a community, the collective agreement of the legal representatives of the group or community concerned must be sought. Nevertheless, the refusal of the individual to participate in the research must be respected.</u></p>
CANADA	I	D	<p>Article 10 – Informed Consent</p>
		A	<p>a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty. <u>Consent may be waived in exceptional circumstances, where the risk to the research subject is minimal and prior approval is obtained from ethics committee.</u></p>
		M	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the <u>free and informed</u> consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person. <u>Consent may be prior and express or be implied from the decision of the person to allow the diagnosis or treatment to proceed. Such consent may be withdrawn by the person concerned at any time and for any reason.</u></p>
		A	
		M	<p>c) In any <u>research or medical</u> decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons, <u>the interest of such persons should be protected by appropriate safeguards by law.</u> Such protection shall be based on ethical and legal standards adopted by <u>of</u> States, consistent with the principles set out in this Declaration.</p>
CYPRUS	II	M	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person <u>Any intervention for diagnostic or therapeutic reasons on a human being</u> shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.</p>
GERMANY	II	M	<p>a) Any decision or practice in the field of Scientific research <u>in the field of medicine and life sciences shall should</u> only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.</p>
		M	<p>b) Any decision or practice regarding the <u>Medical</u> diagnosis and treatment of a person shall only be made or carried out with the <u>prior and free</u> consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person. The</p>

		<p>A <u>consent should, where appropriate, be express in the case of major medical interventions. Such consent may be withdrawn by the person concerned at any time and for any reason without disadvantage or penalty.</u></p> <p>M c) In any decision or practice involving pPersons who do not have the capacity to consent, <u>should be given utmost special protection shall be given to such persons.</u> Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration <u>fulfilling the following criteria: no alternative of comparable effectiveness, potential of direct benefit, ethical review, information of the person concerned as far as possible and complete information of the respective legal representatives or duly authorized body, consent by legal representative and/or by authorized body provided for by domestic law, no objection by the person concerned; in case of research with no potential direct benefit to the person concerned additional conditions of potential benefit to other persons in the same age category or afflicted with the same disease and minimal risk and minimal burden for the person concerned.</u></p> <p>C Art. 10 a), b),c) <i>In any case, the dignity and autonomy of the person demands that no person shall be subjected to medical diagnosis and treatment or to research in a way that could reduce the person to a mere object of medicine or research, respectively of the will of medical or research personnel. Therefore prior free consent of the person, based on information appropriate to the decision, is a necessary condition. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty. The consent must - in addition - be express in the case of research and in appropriate cases of medical treatment or diagnosis. Any research project involving human beings must also be subjected to ethical evaluation by an ethics commission at the appropriate level (as provided for in Art. 20).</i></p> <p><i>Art. 10c) These very sensitive issues require utmost conscientiousness and accuracy. Art. 10 c) does not differentiate between medical diagnosis/treatment and research as 10 a) and b) do for persons able to consent. It stipulates only that persons who do not have the capacity to consent shall be given special protection. Everything else is left to the decision of states consistent with the principles of the Declaration. No indication is given as to the nature of this protection. The Draft, which under a) and b) stipulates principles for the protection of persons able to consent, does not mention any additional specific principles/criteria for the group of those unable to consent, who are more vulnerable and therefore need more protection. Thus the Draft fails to fulfill its aim to give guidance. Germany therefore includes a list of the necessary principles/criteria below in the proposed amendments to Art. 10c).</i></p> <p><i>Whereas it is generally accepted that, also in the case of persons unable to consent, research with a potential direct benefit to the person concerned should be permitted under strict conditions, there is an intense debate in Germany as to whether there can be any ethical justification for authorizing research on such persons that does not have an expected direct health benefit to the person concerned. Under German law such research on adult persons is generally considered as inadmissible. In clinical trials on drugs it may be carried out on minors and in exceptional cases and with the utmost restraint, under the condition that the research is intended to contribute to the health benefit of other persons in the same age category or with the same medical condition and that the research exposes the person only to a minimal risk and minimal burden. Germany holds the view, that - if research without the potential of a direct benefit shall be allowed by</i></p>
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			<p><i>national law for persons, who do not have the capacity to consent for reasons of age (minors), disease or disablement - there must be modifications and additional requirements. The Declaration should contain additional principles/criteria aiming at the highest possible protection standard. Utmost protection must be guaranteed by law consistent with the principles set out in this Declaration.</i></p>
ICELAND	II	C	<p><i>Article 10a) and article 11 are of some concern to Iceland. We wonder if they do sufficiently consider possible population-based and/or epidemiological studies based on patient data which have been collected, for instance the cancer register in Iceland to take one example. The validity of such research may be contingent on the non-skewness of a sample. Despite the fact that most of such research utilises irretrievably unidentifiable data, it is foreseeable that future studies seek to use coded data in a similar fashion.</i></p> <p><i>The concept of unidentifiable data, be it within an epidemiological context or within the framework of for instance surveys or anonymous questionnaires, is relative - anonymity in a large community is not necessarily extrapolated into a small community. For small societies, like Iceland or indigenous societies worldwide, the considerations are certainly relevant and could possibly be addressed here in a clearer fashion.</i></p> <p><i>We suppose that there are not contradictions between these articles and for instance articles 8 to 12 in the International Declaration of Genetic Data and the Helsinki Declaration. But if so, these articles need to be modified.</i></p>
INDIA	I	A	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person, particularly invasive, shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision and with the ongoing participation of such person.</p>
JAPAN	II	M	<p>a) Any decision or practice in the field of scientific research shall should only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.</p>
		M	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person shall should only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.</p>
		M	<p>c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall should be given to such persons. Such protection shall should be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration.</p>
MEXICO	I	A	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person. <u>In further decisions, based on a constant communication, the person's consent may be withdrawn by the person at any time.</u></p>
		A	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person. <u>In further decisions, based on a constant communication, the person's consent may be withdrawn by</u></p>

		A	<p><u>the person at any time.</u></p> <p>c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration <u>and other relevant document.</u></p>
MONACO	II	D	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.</p> <p>C</p> <p>The obligation of ongoing participation of the person in medical decisions and practice is unrealistic. In effect, once consent has been obtained, it would be a constraint on the practitioner to have to request for each act, however minor, a renewal of consent. That is however the form that the participation set out in the text could take in the opinion of some people. Once “appropriate information” has been given and consent obtained, it would be excessive to require more.</p>
NETHERLANDS	I	M	<p>c) In any decision or practice involving persons who do not have the capacity to consent, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration. <u>In any case, such practices may only be carried out for the direct benefit of these persons or, if benefit is absent, only with a minimal risk and minimal burden.</u></p>
PORTUGAL	I	A	<p>a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed, <u>adequate</u> and express consent <u>taking into account the cultural and educational level</u> of the persons concerned.</p> <p>A</p> <p>b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision <u>and certified as clearly understood,</u> and with the ongoing participation of such person.</p>
ROMANIA	II	C	<p><i>In subparagraph (c): introduce the notion of “emergency intervention” concerning prior consent in the case of persons incapable of expressing consent.</i></p>
SAUDI ARABIA	I	A	<p>b) Any decision or practice regarding the medical diagnosis and treatment of a person, <u>particularly invasive,</u> shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.</p> <p>C</p> <p><i>Support the proposal for using b, c, d of Article 8 of the International Declaration on Human Genetic Data.</i></p>
SYRIA	I	M	<p>a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.</p> <p><u>a) Research treatment or diagnosis may not be carried out without the prior, free, informed and express consent, based on appropriate information, of the person concerned. Such consent may be withdrawn by the person concerned at any time. If the person concerned does not have the capacity to consent, such consent shall be obtained in accordance with national law and shall be guided by the higher interest</u></p>

		M	<p><u>if the person concerned.</u></p> <p>b) Any decision or practice regarding the medical diagnosis and treatment of a person shall only be made or carried out with the consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person.</p> <p>b) If, in accordance with national law, a person does not have the capacity to consent that person shall benefit from special protection which shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration.</p>
TURKEY	I	M	<p>c) In any decision or practice involving persons who do not have the capacity to consent persons not able to consent and persons who have a serious mental disorder, special protection shall be given to such persons. Such protection shall be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration.</p>
UGANDA	I	A	<p>a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent shall be arrived at without undue pressure or manipulation. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.</p>
UNITED KINGDOM	II	M	<p>a) Any decision or practice in the field of scientific research shall only be made or carried out with the prior, free, informed and express consent of the persons concerned. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty capable persons concerned. The person or people consenting should be made aware of how and if they may withdraw their consent.</p>
UNITED STATES OF AMERICA	II	M	<p>a) Any decision or practice in the field of Scientific research involving human subjects shall should only be made or carried out with the prior, free, informed and express consent of the persons concerned, except as provided for in domestic law, consistent with the protection of human life, dignity and autonomy. Such consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or penalty.</p>
		M	<p>b) Any decision or practice regarding the Medical diagnosis and or treatment of a person shall should only be made or carried out with the prior, free, informed and express consent of the person concerned, based on information appropriate to the decision, and with the ongoing participation of such person, except as provided for in domestic law, consistent with the protection of human life, dignity and autonomy.</p>
		M	<p>c) In any decision or practice involving persons Individuals who do not have the capacity to consent, special protection shall should be given to such persons special protection, including provisions for substitute consent by a representative of the individual and implied consent in emergency situations. Such protection shall should be based on ethical and legal standards adopted by States, consistent with the principles set out in this Declaration protection of human life, dignity and autonomy.</p>

Article 11 – Privacy and Confidentiality

Any decision or practice shall be made or carried out with respect for the privacy of the persons concerned and the

confidentiality of their personal information. Unless irretrievably unlinked to an identifiable person, such information shall not be used or disclosed for purposes other than those for which it was collected.

AUSTRALIA	C	<i>The article should be reworded by including a domestic law exception.</i>
GERMANY	M	Any decision or practice shall be made or carried out with respect for The right to privacy of the persons concerned and the confidentiality of their personal <u>data</u> information <u>should be fully respected</u>. Unless irretrievably unlinked to an identifiable person, such information shall data should not be used or disclosed for purposes other than those for which it was collected, <u>except with the prior, free, informed and express consent of the person concerned</u> .
JAPAN	M	Any decision or practice shall should be made or carried out with respect for the privacy of the persons concerned and the confidentiality of their personal information. Unless irretrievably unlinked to an identifiable person, such information shall should not be used or disclosed for purposes other than those for which it was collected.
UNITED KINGDOM	A	Any decision or practice shall be made or carried out with respect for the privacy of the persons concerned and the confidentiality of their personal information. Unless irretrievably unlinked to an identifiable person, such information shall not be used or disclosed for purposes other than for which it was collected <u>except where relevant in accordance with professional obligations and standards, and domestic law</u> .

Article 12 – Solidarity and Cooperation

Any decision or practice shall pay due regard to solidarity among human beings and encourage international cooperation to that end.

AUSTRALIA	C	<i>The interpretation of this article would be assisted if it more clearly adopted the language used in the International Covenant on Economic, Social and Cultural Rights, in particular Article 12 which refers to “the right to the highest attainable standard of health”.</i>
CANADA	A	Any decision or practice shall pay due regard to solidarity among human beings and encourage international cooperation to that end, <u>with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources</u> .
	C	<i>Canada is suggesting that paragraph (c) of article 26 be removed because it addresses the same subject-matter as article 12 – solidarity. However, the highlighted phrase, which currently appears in article 26(c), should be preserved by adding it to article 12.</i>
GERMANY	M	Any decision or practice shall pay due regard to Solidarity among human beings <u>should be paid due regard</u> and encourage international cooperation to that end <u>should be encouraged</u>.
JAPAN	M	Any decision or practice shall should pay due regard to solidarity among human beings and encourage international cooperation to that end.

Article 13 – Social Responsibility

Any decision or practice shall ensure that progress in science and technology contributes, wherever possible, to the

common good, including in the achievement of goals such as:

- (i) access to quality health care and essential medicines, including for reproductive health and the health of children;
- (ii) access to adequate nutrition and water;
- (iii) improvement of living conditions and the environment;
- (iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and
- (v) reduction of poverty and illiteracy.

CANADA	M	(iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds discrimination and protection of equality;
GERMANY	M	<p>Any decision or practice shall ensure that progress in science and technology contributes, wherever possible, to the common good, including in the achievement of goals such as:</p> <p>(i) Access to quality health care and essential medicines, (including for reproductive health and the health of children); and the right to benefit from medical treatment under the conditions established by national law and practices should be ensured.</p> <p>(ii) access to adequate nutrition and water;</p> <p>(iii) improvement of living conditions and the environment;</p> <p>(iv) elimination of the marginalization and the exclusion of persons on the basis of any grounds; and</p> <p>(v) reduction of poverty and illiteracy.</p>
JAPAN	M	<p>Any decision or practice shall should ensure that progress in science and technology contributes, wherever possible, to the common good, including in the achievement of goals such as:...</p>
MONACO	C	<p><i>It is obvious that access to health care is applicable to all patients. It is therefore superfluous to refer also to reproductive health and the health of children.</i></p>
ROMANIA	A	<p>NEW (vi) access to end-of-life palliative care for patients (terminal phases).</p>

Article 14 – Sharing of Benefits

a) Benefits resulting from scientific research and its applications shall be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

- (i) special and sustainable assistance to the persons and groups that have taken part in the research;
- (ii) access to quality health care;
- (iii) provision of new diagnostics, facilities for new treatments or medical products stemming from the research;
- (iv) support for health services;
- (v) access to scientific and technological knowledge;
- (vi) capacity-building facilities for research purposes; and
- (vii) any other form consistent with the principles set out in this Declaration.

b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.

<p>AUSTRALIA</p>	<p>M</p> <p>C</p>	<p>a) <u>In accordance with international and domestic law, benefits</u> resulting from scientific research and its applications shall should be shared with society as a whole and within the international community...</p> <p>b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.</p> <p><i>This article may be inconsistent with the TRIPS agreement and the use of the word “shall” in 14 (a) and 14 (b) is considered too prescriptive. We look forward to removing these difficulties through drafting. We also want to make it clear that obligations under existing domestic and international IP agreement and treaties will necessarily impact on any benefit sharing provision of this instrument. It is also very important that domestic law, implementing existing international obligations, is not rendered subservient to the sharing of benefits principle in this instrument. We believe that the last phrase may not be adequate to ensure consistency between this instrument and existing obligations under international IP instruments.</i></p>
<p>BOLIVIA</p>	<p>M</p> <p>A</p>	<p>a) <u>In accordance with international and domestic law, benefits</u> resulting from any scientific research and its applications shall be shared with the whole of society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms: <u>To give effect to that principle the benefits may have the following features or forms:</u></p> <p>...</p> <p>NEW (vi) respect for the free choice and the interest and needs of beneficiaries;</p> <p>NEW (vii) benefit in direct relation to the requirements of the beneficiary;</p> <p>(viii) (viii) capacity-building facilities for research purposes; and</p> <p>(vii) (ix) any other form consistent with the principles set out in this Declaration.</p>
<p>CANADA</p>	<p>A</p>	<p><u>NEW b) Benefits shall not constitute improper inducements to participate in scientific and medical research contrary to the principles of free consent.</u></p> <p>b) c) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.</p>

	C	<i>There is concern that some forms of benefits might in some circumstances constitute improper inducements to participate in research, contrary to the criteria of free consent as set out in article 10.</i>
GERMANY	M	<p>a) Benefits resulting from scientific research in medicine and life sciences and its applications shall should be shared with society as a whole and within the international community, in particular with developing countries, <u>in accordance with domestic law or policy and international agreements.</u> In giving effect to this principle, benefits may take any of the following forms:</p> <ul style="list-style-type: none"> (i) special and sustainable assistance to the persons and groups that have taken part in the research; (ii) access to quality health care; (iii) provision of new diagnostics, facilities for new treatments or medical products stemming from the research; (iv) support for health services; (v) access to scientific and technological knowledge; (vi) capacity-building facilities for research purposes; and <u>(vi bis) developing and strengthening the capacity of developing countries in the field of life sciences, taking into consideration their specific problems; and</u> (vii) any other form consistent with the principles set out in this Declaration.
	M	<p>b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law. <u>Limitations in this respect could be provided by domestic law and international agreements.</u></p>
	C	<p><i>Article 14 should be amended in line with the wording in Article 19 of the UNESCO Declaration on Human Genetic Data.</i> <i>“Research” has to be specified: in medicine and life sciences.</i> <i>b) should be deleted as implementation is dealt with in another section of the declaration. Limitations by domestic and international law have to be mentioned instead.</i> <i>The need for developing and strengthening the capacity of developing countries in the field of life sciences should be specifically mentioned.</i></p>
JAPAN	M	<p>a) Benefits resulting from scientific research and its applications shall should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:</p>
	D	<ul style="list-style-type: none"> (i) special and sustainable assistance to the persons and groups that have taken part in the research; (ii) access to quality health care; (iii) provision of new diagnostics, facilities for new treatments or medical products stemming from the research; (iv) support for health services; (v) access to scientific and technological knowledge; (vi) capacity-building facilities for research purposes; and (vii) any other form consistent with the principles set out in this Declaration. <p>b) This provision may be implemented through legislation, international agreements or by other appropriate means, which shall be consistent in every case with international human rights law.</p>
UNITED KINGDOM	M	<p>b) This provision may be implemented through legislation, international agreements <u>domestic law and international agreements</u> or by other appropriate means, which shall be consistent in every case with international human rights law.</p>

Article 15 – Responsibility towards the Biosphere

Any decision or practice shall have regard to its impact on all forms of life and their interconnections and to the special responsibility of human beings for the protection of the environment, biodiversity and the biosphere.

GERMANY	M	Any decision or practice shall have regard to its impact on all forms of life and their interconnections should be given due regard and to in view of the special responsibility of human beings for the protection of the environment, biodiversity and the biosphere, including animal welfare .
JAPAN	D	Article 15 – Responsibility towards the Biosphere Any decision or practice shall have regard to its impact on all forms of life and their interconnections and to the special responsibility of human beings for the protection of the environment, biodiversity and the biosphere.
ROMANIA	A	Any decision or practice shall have regard to its impact on all forms of life and their interconnections and to the special responsibility of human beings, individuals, families, groups, communities, public and private bodies and society as a whole for the protection of the environment, biodiversity and the biosphere.

CONDITIONS FOR IMPLEMENTATION

GERMANY	C	<p><i>Articles 16 - 19 require general revision.</i></p> <p><i>The specific meaning and the addressees of the various implementation principles remain unclear. E.g. “transparently and openly” and “after public debate” could not apply to commercial research. There are some principles that can be feasibly applied in academic research but would cause problems in the field of commercial research. Other principles are addressed, for example, also to individual doctors or the member states. Here, too, the phrase “Any decision or practice” as an introductory formula should be avoided. The enumeration of rules referring to different actors, who are not mentioned, leads to confusion.</i></p> <p><i>Risk assessment refers to technology and environment (see Art.22) and therefore is not the proper category applicable to bioethics. To address the issue of risks in medicine and the life sciences we propose to amend Article 16 (v) so as to place greater emphasis on the concept of risk and burden evaluation as relevant in relation to human beings.</i></p> <p><i>Without having clarified the problem of the separate spheres for separate principles, we are not yet in a position to propose an alternative wording for art. 16-19 beyond that, but intend to do so, once the problem of addressees has been solved.</i></p>
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Article 16 – Decision-Making

Any decision or practice should:

- (i) be made or carried out following full and free discussion and in accordance with fair procedures;
- (ii) be made or carried out on the best available scientific evidence and methodology;
- (iii) pay due regard to any different information on the subject reasonably available to the decision-maker;
- (iv) be considered rigorously and based on the principles set out in this Declaration;
- (v) observe, when appropriate, proper procedures of risk assessment, management and prevention; and
- (vi) be considered individually, having regard to the circumstances of the persons, groups and communities concerned.

AUSTRALIA	A	<u>NEW (vii): be consistent with national and international law.</u>
BOLIVIA	D	(v) observe when appropriate, proper procedures of risk assessment management and prevention; and
CANADA	M	Any decision or practice should: (i) be made or carried out following full and free discussion <u>among interested parties and in accordance with fair procedures;</u> (ii) be made or carried out on the best available scientific evidence and methodology; (iii) pay due regard to any different information on the subject reasonably available to the decision maker; (iv) be considered rigorously and based on the principles set out in this Declaration; (v) observe, when appropriate, proper procedures of risk assessment, management and prevention; and (vi) be considered individually, having regard to the circumstances of the persons, groups and communities concerned; <u>(ii) pay due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society;</u> <u>(iii) be susceptible to informed, wide and pluralistic public debate.</u>
GERMANY	D	[Any decision or practice] should: ...
	M	(v) observe, when appropriate, proper procedures of risk assessment, management and prevention should not involve risks and burdens to the human being disproportionate to its potential benefits; and ...

Article 17 – Honesty and Integrity

Any decision or practice should be made or carried out with:

- (i) professionalism, honesty and integrity;
- (ii) declaration of all conflicts of interest; and
- (iii) due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society.

AUSTRALIA	C	<i>There needs to be clarification regarding consistency with TRIPS.</i>
CANADA	M	Any decision or practice should: (i) professionalism, honesty and integrity; (ii) declaration of all conflicts of interest; and (iii) due regard to the need to share knowledge about such decisions and practices with the persons affected, the scientific community, relevant bodies and civil society; <u>(i) be made and carried out openly, with professionalism, honesty, integrity and transparency as to possible or apparent conflicts of interest;</u> <u>(ii) be available for appropriate scrutiny by the persons concerned and by civil society;</u>

GERMANY	M	[Any decision or practice] should be made or carried out with:...
MONACO	M	Any decision or practice should be made or and carried out with: ...
	C	<i>A measure may be decided fully in accordance with ethics and applied in total disregard for the principles set out. This is the same problem as the one identified regarding the words “decisions or practices”.</i>

Article 18 – Transparency

Any decision or practice should, subject to the provisions on privacy and confidentiality in Article 11:

- (i) be made or carried out transparently and openly;
- (ii) be available for appropriate scrutiny by the persons concerned and by civil society; and
- (iii) be susceptible to informed, wide and pluralistic public debate.

BOLIVIA	A	(iii) be susceptible to informed, wide and pluralistic public debate, <u>including in the media.</u>
CANADA	M	Any decision or practice should, subject to the provisions on privacy and confidentiality in Article 11: (i) be made or carried out transparently and openly; (ii) be available for appropriate scrutiny by the persons concerned and by civil society; and (iii) be susceptible to informed, wide and pluralistic public debate. <u>(i) be made or carried out on the best available scientific evidence and methodology under the circumstances;</u> <u>(ii) pay due regard to the diversity of information on the subject reasonably available to the decision-maker;</u> <u>(iii) observe, when appropriate, proper procedures of risk assessment, management and prevention;</u>
GERMANY	M	[Any decision or practice] should, subject to the provisions on privacy and confidentiality in Article 11:...
	C	<i>Problems include: private research, public debate about doctor’s decisions?</i>
JAPAN	D	Any decision or practice should, subject to the provisions on privacy and confidentiality in Article 11: (i) be made or carried out transparently and openly; (ii) be available for appropriate scrutiny by the persons concerned and by civil society; and (iii) be susceptible to informed, wide and pluralistic public debate.

MONACO	M	(i) be made or and carried out transparently and openly;
	C	<i>A measure may be decided fully in accordance with ethics and applied in total disregard for the principles set out. This is the same problem as the one identified regarding the words “decisions or practices”.</i>

Article 19 – Periodic Review

Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with:

- (i) persons affected by any such decision or practice;
- (ii) members of relevant disciplines;
- (iii) appropriate bodies; and
- (iv) civil society.

AUSTRALIA	C	<i>It is unclear whether this article is aimed at States, individuals or companies and, at any rate, requires amendment to make it clear that periodic reviews and dialogue would be conducted on a voluntary basis.</i>
BOLIVIA	A	NEW (v) governmental bodies.
CANADA	M	Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with individuals, professionals, groups, communities, institutions and corporations, public and private. (i) persons affected by any such decision or practice; (ii) members of relevant disciplines; (iii) appropriate bodies; and (iv) civil society.
GERMANY	D	Article 19 – Periodic Review Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue with: (i) persons affected by any such decision or practice; (ii) members of relevant disciplines; (iii) appropriate bodies; and (iv) civil society.
	C	<i>Art. 19 is superfluous, “best available scientific evidence....-” (different information ...) mentioned in 16 ii u. iii and Art. 21 (Public debate) and therefore should be dropped entirely.</i> <i>Art. 19 if applied to individuals could have absurd consequences: should a doctor according to a) have a regular dialogue with a former patient?</i>
JAPAN	M	Article 19 – Periodic Review Reconsideration Any decision or practice, including those depending upon specialized scientific or other knowledge, should take into account the need to reconsider periodically the state of such knowledge and different opinions about it and the need to engage in a regular dialogue, when appropriate , with:...

Article 20 – Ethics Committees

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

- (i) assess the ethical, legal and social issues related to scientific research projects involving human beings;
- (ii) formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration, in accordance with the principles set out herein; and
- (iii) foster debate and education in bioethics.

AUSTRALIA	C	<i>The language is unclear and too prescriptive.</i>
ROMANIA	A	(i) assess the ethical/ <u>moral</u> , legal and social issues related to scientific research projects involving human beings;
	C	<i>The document makes use only of the term “ethics”. Moral, system of values emerging from religious tradition has also to be acknowledged or we will get only the secular bioethics perspective and loose the other possible approach.</i>
UNITED KINGDOM	A	Independent, multidisciplinary and pluralist ethics committees should be established, promoted and support at the appropriate level in order to: i) assess the relevant ethical, legal and social issues related to scientific research projects involving human beings; ii) where relevant, to formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration, in accordance with the principles set out therein
	M	iii) foster debate, and education and public engagement in bioethics.

Article 21 – Promoting Public Debate

States should promote opportunities for informed, pluralistic public debate, ensuring the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.

AUSTRALIA	M	States should promote opportunities for informed, pluralistic public debate, ensuring encouraging the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.
	C	<i>This would better reflect the idea of promoting debate, and would be more consistent with the language in (the related) Article 25 on Bioethics Education, Training and Information.</i>
GERMANY	A	States should promote opportunities for informed, pluralistic public debate, encouraging the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.

JAPAN	M	States should promote opportunities for informed, pluralistic public debate, ensuring <u>Opportunities for informed, pluralistic public debate at appropriate levels should be promoted with</u> the participation of all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.
UNITED KINGDOM	M	States should ensure that citizens have an opportunity for informed, pluralistic debate, ensuring the participation of <u>and participation should be open to</u> all persons and bodies concerned, including relevant ethics committees and non-governmental organizations, and the expression of various socio-cultural, religious, philosophical and other relevant opinions.

Article 22 – Risk Assessment, Management and Prevention

- a) When evidence of serious or irreversible damage to public health or human welfare becomes available, appropriate measures should be taken in a timely manner.
- b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms.

AUSTRALIA	D	b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms.
	C	<i>As the article introduces the concept of risk that is clearly not defined, the article must make clear that “risks” are explicitly confined to risks related to decisions and practices addressed in this Declaration.</i>
CANADA	A	<u>NEW a) States should establish a process for the assessment, management and prevention of risks. Such processes 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.</u> ⇒ <u>b)</u> When evidence of serious or irreversible damage ... ⇒ <u>c)</u> When there are threats of serious or irreversible damage ...
	C	<i>Canada is of the view that paragraph (c) of article 24 should be moved to become a new paragraph (a) of article 22. Paragraph (c) of article 24 pertains to risk management and is general in scope. The current paragraphs of article 22 pertain to risk management in exceptional circumstances. For this reason, these provisions should be placed together in the same article and in the proposed order. The current paragraphs of article 22 would be re-numbered.</i>

<p>GERMANY</p>	<p>D</p> <p>C</p>	<p>Article 22 – Risk Assessment, Management and Prevention</p> <p>a) When evidence of serious or irreversible damage to public health or human welfare becomes available, appropriate measures should be taken in a timely manner.</p> <p>b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms.</p> <p>Articles 22 and 24 (c) Risk Assessment as such is not applicable to bioethics issues. Article 22 again highlights the problems concerning scope which were pointed out earlier on. A catch-all article on risk assessment covering the whole spectrum of applications is liable to cause problems by blurring the existing separate and distinct criteria for assessing either medical and life sciences issues or issues of science, technology and environment. The bioethical debate on ethical, legal and social questions and the ethical evaluation of biomedical developments in particular cannot be approached in the same way as the debate on risk assessment issues arising from new technologies, i.e. how public policy can ensure the necessary protection for the human person and the environment on the basis of rational and scientifically sound criteria that are actionable under law.</p> <p>Where medical and life sciences applications to the human person are concerned, risk assessment is based on special standards specific to such cases. These are reflected, for example, in the considerations relating to beneficence and non-maleficence in Article 6 and, by the same token, they inform the work of ethics committees in assessing research projects.</p> <p>In the biomedical field the need to prevent risks to others in connection, for example, with xenotransplants or certain forms of gene therapy, is a problem well recognized in medical circles as far as preventing infection is concerned. International guidelines (e.g. WHO, EU, CoE) addressing specific issues in this area already exist.</p> <p>Since the Declaration should not cover in detail environmental issues the concept of risk assessment seems to be out of place.</p> <p>Germany therefore proposes that Articles 22 and 24 (c) should be deleted and Article 16 (v) be amended instead (see there). If necessary Art. 24 c) could be retained if Art. 22 is deleted.</p>
<p>JAPAN</p>	<p>D</p>	<p>Article 22 – Risk Assessment, Management and Prevention</p> <p>a) When evidence of serious or irreversible damage to public health or human welfare becomes available, appropriate measures should be taken in a timely manner.</p> <p>b) When there are threats of serious or irreversible damage to public health or human welfare, and there is not yet scientific certainty about such threats, provisional, adequate and proportionate measures should be taken in a timely manner. Such measures should be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect for human dignity, human rights and fundamental freedoms.</p>

Article 23 – Transnational Practices

- a) States should take appropriate measures to ensure that any activity with bioethical implications, which is undertaken in whole or in part in different States, complies with the principles of this Declaration. Public and private institutions and professionals associated with a transnational activity should also take all appropriate measures to achieve the same end.
- b) When research is carried out in one country and funded partially or wholly by sources from one or more other countries, such research should be subjected to ethical review in all of the countries involved. This review should be based on ethical and legal standards, consistent with the principles set out in this Declaration, adopted by the States concerned.

<p>AUSTRALIA</p>	<p>M</p> <p>D</p> <p>C</p>	<p>a) States, as well as public and private institutions associated with a transnational activity, should take appropriate measures endeavour to ensure that any activity with bioethical implications, which is undertaken in whole or in part in different States, complies with the principles of this Declaration. Public and private institutions and professionals associated with a transnational activity should also take all appropriate measures to achieve the same end.</p> <p>b) When research is carried out in one country and funded partially or wholly by sources from one or more other countries, such research should be subjected to ethical review in all of the countries involved. This review should be based on ethical and legal standards, consistent with the principles set out in this Declaration, adopted by the States concerned.</p> <p><i>Note, however, that the phrase ‘any activity with bioethical implications’ may be too broad and could possibly be replaced with the term ‘decision or practice’ which is emerging from “descriptions” in Articles 1 and 2. 23(b) is unrealistic, resource intensive and impractical.</i></p>
<p>CANADA</p>	<p>M</p>	<p>a) States should take appropriate measures to ensure that any activity with bioethical implications, which is undertaken in whole or in part in different States, complies with the principles of this Declaration. Public and private institutions and professionals Individuals, professionals, groups, communities, institutions and corporations, public and private, associated with a transnational activity should also take all appropriate measures to achieve the same end.</p>
<p>GERMANY</p>	<p>C</p>	<p><i>Question: In Art. 23 private institutions and professionals are obliged to subject projects to ethical review in all the countries involved. What does this imply in case one of the states has not passed any legislation or rules on ethical review?</i></p>
<p>UNITED KINGDOM</p>	<p>M</p>	<p>b) When research is carried out in one country and funded partially or wholly by sources from one or more other countries, such research should be subjected to an appropriate level of ethical review in all the countries involved. This review should be based on ethical and legal standards, consistent with the principles set out in this Declaration, adopted by the States concerned.</p>

IMPLEMENTATION AND PROMOTION OF THE DECLARATION

<p>GERMANY</p>	<p>C</p>	<p><i>Inconsistency: Role of States addressed in Art. 24, 25 and 26, but mentioned only in title 24.</i></p>
<p>RUSSIAN FEDERATION</p>	<p>M</p> <p>C</p>	<p>Implementation Accomplishment and Promotion of the Declaration</p> <p><i>The title of one chapter is “Conditions for Implementation”; the title of the next one is “Implementation and Promotion of the Declaration”. The word “implementation”.</i></p>

		<i>which is used in both cases, has two different meanings: implementation of principles in the first case and implementation of the declaration as such in the second case. It could create grounds for misinterpretation and confusions.</i>
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Article 24 – Role of States

- a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information. States should also take appropriate measures to involve young people in these activities.
- b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, in accordance with Article 20.
- c) States should establish processes for the assessment, management and prevention of risks. Such processes 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>AUSTRALIA</p>	<p>D</p> <p>A</p> <p>C</p>	<p>a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with international human rights law....</p> <p>...</p> <p>c) Where appropriate, States should establish processes...</p> <p><i>The former formulation of a) would ensure that activity under the WTO was consistent with WTO and trading rules, as well as with human rights law.</i></p>
<p>CANADA</p>	<p>D</p> <p>D</p> <p>D</p> <p>C</p>	<p>a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information. States should also take appropriate measures to involve young people in these activities.</p> <p>b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, in accordance with Article 20.</p> <p>c) States should establish processes for the assessment, management and prevention of risks. Such processes 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><i>In order to avoid duplication, the last two sentences of paragraph (a) should be deleted from the text, as they pertain to the same subject-matter as article 25 – education on bioethics issues. Paragraph (b) – pertaining to ethics committees - should be removed entirely, as it is duplicative of article 20. Finally, if agreement is reached to move paragraph (c) to article 22, this paragraph should be removed from article 24. If agreement is not reached, this paragraph should remain in article 24.</i></p>
<p>GERMANY</p>	<p>D</p>	<p>a) States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration, in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information. States should also take appropriate measures to involve young people in these activities.</p> <p>b) States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, in accordance with Article 20.</p>

	C	<p>e) States should establish processes for the assessment, management and prevention of risks. Such processes 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>Risk assessment see above: If necessary Art. 24 c) could be retained if Art. 22 is deleted.</p>
JAPAN	D	<p>e) States should establish processes for the assessment, management and prevention of risks. Such processes 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>
ROMANIA	A	<p><u>NEW d) States should retain their right to forbid on their territory on scientific and/or cultural basis activities and/or procedures regarded to present material and/or ethical/moral concern even if those activities and/or procedures have been approved by other States and/or international regulations.</u></p>
	C	<p><i>This should enable particular more detailed options and more protective policies. Besides, there is a precedent of this kind, in the European legislation regarding GMOs, namely in 2001/18/EC. A State can place an interdiction upon a GMO that is revealed to present risk for human health or the environment even if the GMO's use was approved under European regulations.</i></p>

Article 26 – International Cooperation

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

AUSTRALIA	A	<p>c) States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources, <u>in a manner consistent with international and domestic law.</u></p>
	C	<p><i>Language is too prescriptive and possibly inconsistent with TRIPS. To further reiterate the need for this instrument to take into account existing obligations under domestic and international laws.</i></p>
BOLIVIA	M	<p>c) States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for <u>based on the universal principle of equality and preference for the needs of</u> those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.</p>
CANADA	D	<p>a) States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.</p>

		<p>b) Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.</p> <p>e) States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.</p> <p>C <i>In order to avoid duplication, paragraph (a) should be removed, as it addresses an issue already addressed in articles 13 and 14 – the dissemination of scientific information. Similarly, paragraph (c) should be removed because it addresses solidarity, an issue already dealt with in article 12. As noted above, the phrase “with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources” should, however, be added to article 12.</i></p>
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Article 27 – Roles of the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC)

- a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out herein. 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.
- b) Reports provided by States, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO.

CANADA	D	<p>b) Reports provided by States, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO.</p>
GERMANY	D	<p>a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out herein. 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, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO.</p> <p>C <i>As regards Article 27, it is obviously the role of UNESCO’s bioethics committees IBC and IGBC to promote and monitor the implementation of the Declaration. Since this goes without saying, an explicit reaffirmation would be redundant. Germany is opposed, moreover, to states having to provide regular reports in this connection. We propose therefore that the Article should end with the first sentence. Keeping track of implementation by requesting member states’ to inform UNESCO ad-</i></p>

		<i>hoc on any legislation/regulations - existing or when entering into force, to be published on UNESCO Bioethics website is a much more effective and efficient way of monitoring continuously.</i>
INDONESIA	M	a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out herein. 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 IBC and IGBC should monitor, evaluate, and make recommendations in accordance with UNESCO's statutory procedures, addressed to the General Conference.
JAPAN	D	a) The International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC) shall contribute to the implementation of this Declaration and the dissemination of the principles set out herein. 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.
	M	b) Reports provided by States, on the steps they have taken, whether of a legislative, administrative or other character, to give effect to this Declaration, should be addressed every five years to the Director-General of UNESCO <u>at such times and in such manner as shall be determined by the General Conference.</u>

Article 28 – Follow-up action by UNESCO

- a) UNESCO shall take appropriate action to follow up this Declaration by evaluating new developments in science and technology and their applications according to the principles set out herein.
- b) UNESCO shall reaffirm its commitment to dealing with the ethical aspects of the biosphere and, if necessary, shall endeavour to elaborate guidelines and international instruments, as appropriate, on ethical principles related to the environment and other living organisms.
- c) Five years after its adoption and thereafter on a periodical basis, UNESCO shall take appropriate measures to examine this Declaration in the light of scientific and technological development and, if necessary, to ensure its revision, in accordance with UNESCO's statutory procedures.
- d) With respect to the principles set forth herein, this Declaration may be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.

AUSTRALIA	C	<i>In 28 (a), it is not clear what “appropriate action” UNESCO shall take and the reference to the biosphere in 28 (b) is also problematic given the draft declaration’s focus on humans.</i>
CANADA	M	d) With respect to the principles set forth herein, this Declaration may be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO’s statutory procedures. <u>Further international instruments that address bioethical issues may be developed under the auspices of UNESCO in accordance with the principles of this Declaration. The principles established by this Declaration shall be used as required to interpret and apply the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data.</u>

GERMANY	C	<i>Is art 28 b) necessary? Sufficiently covered by d) already.</i>
JAPAN	M	<p>a) UNESCO shall should take appropriate action</p> <p>b) UNESCO shall should reaffirm its commitment</p> <p>c) Five years after its adoption and thereafter on a periodical basis, UNESCO shall should take appropriate measures</p>

OPERATION OF THE PRINCIPLES AND DECLARATION

Article 30 – Restrictions on the Principles

No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law, and which are consistent with international human rights law and necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.

AUSTRALIA	C	<i>As noted above (Articles 10 and 11), it is helpful for the declaration to refer to domestic legislation and pre-existing international law. In Australia's case, the Privacy Act allows for secondary uses of personal information while the Declaration, as presently drafted, would prohibit this. Several amendments have been brought forward which need to be examined to rectify circumstances such as this.</i>
GERMANY	C	In Germany's understanding of Art 30 it shall not and does not allow any hollowing out of certain paramount principles. We also understand international human rights law and national legislation and necessity in a democratic society etc. as cumulative requirements.
INDONESIA	D	Article 30 – Restrictions on the Principles No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law, and which are consistent with international human rights law and necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.
JAPAN	D	No restrictions shall should be placed on the principles set out in this Declaration
UNITED KINGDOM	A	No restrictions shall be placed on the principles set out in this Declaration other than those prescribed by law, and which are consistent with international human rights law and necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection and promotion of the rights and freedoms of others.

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

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

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