



United Nations
Educational, Scientific and
Cultural Organization



THE PRINCIPLE OF RESPECT FOR
HUMAN
VULNERABILITY
AND PERSONAL
INTEGRITY

Report of the International
Bioethics Committee of
UNESCO (IBC)



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INTRODUCTORY REMARKS

Article 8 of the Universal Declaration on Bioethics and Human Rights (2005) enshrines the principle of respect for human vulnerability and personal integrity as a bioethical value of universal concern to the Member States of UNESCO. The specific purpose of Article 8 is to address special vulnerabilities that occur, whether as a consequence of personal disability, environmental burdens or social injustice, in the contexts of healthcare, research and the application of emerging technologies in the biomedical sciences. This Report is the result of three years of reflection by the **International Bioethics Committee of UNESCO (IBC)**.

We are definitely all equally entitled to meet our basic needs related to our health and well-being, but we are certainly not all equally and permanently able to meet all those basic needs of ours.

Over the course of its reflections, the Committee has investigated the multiple ethical implications of this very basic inequality among human beings which is particularly highlighted and exacerbated in the context of advances in the fields of biomedical sciences. As a matter of fact, these advances have opened the way for many new and powerful capacities for the safeguarding of human welfare, but they have also created mechanisms of exploitation and degradation which can take advantage of natural and context-related vulnerabilities.

Vulnerability, in its first and more general sense, is an essential feature of human nature and may therefore boost awareness of a common destiny and responsibility. This Report seeks to elaborate the scope and content of Article 8 of the Declaration of 2005, focusing on special vulnerabilities and taking into account conditions that, more or less directly, impinge upon the capacity to live as free and autonomous individuals; and on the right to live in a world where significant inequalities in the capacity to meet everyone's basic needs are adequately addressed.

In writing this report, which is neither exhaustive, nor prescriptive, the ethicists, geneticists, biologists, lawyers, philosophers, psychiatrists, neurologists and immunologists composing the IBC aimed at paving the way for a broader reflexion and indicating possible lines of action not only for States, but also for individuals, groups, communities, institutions and corporations, public as well as private.

They specifically call on all concerned stakeholders to exercise great vigilance in protecting those who are especially vulnerable. Nearly every country of the world is the home of one or the other type of vulnerable groups: countries in which proper antiretroviral therapies are for various reasons not being provided to a majority of HIV/AIDS infected people; countries in which poor patients are refused healthcare because they lack insurance coverage; countries in which people are involved in clinical trials without respecting the principle of free and informed consent, just for the sake of profit. Unfortunately, the list is easy to extend.

Special Vulnerabilities of Women and Girls

Gender-related vulnerabilities and in particular the special vulnerabilities of women and girls have always been in the forefront of the Committee's reflections throughout its work on this publication. Females, both children and women, are given special attention in the Report. Seven of the eighteen cases proposed for discussion specifically refer to the treatment of women in healthcare delivery,

research and the applications of new biotechnologies. Female cases are prominent as they are particularly exposed to the whole range of the social, cultural, economic, educational and political determinants of vulnerability. This is also highlighted in one of the concluding paragraphs of the Report:

“A further important example of special vulnerabilities can be provided using the example of the position of women. In some cultures, female children are uniquely vulnerable to the risk of being unwanted, uncared for, abused and rejected. Female children may also find their interest in bodily integrity gravely threatened, including especially their right to be free from sexual assault and exploitation. Adult women may find themselves transferred from the patronage of their father to the patronage of their husband, thereby denying them the personal authority to make important life and healthcare decisions on their own behalf. As women live longer in many parts of the world, elderly women might find themselves abandoned by their families, subject to inadequate healthcare, and disregarded by society. Migrant women and women affected by war are especially vulnerable to abuse and are often disenfranchised from engaging in conflict resolution and reconciliation.”

Special Vulnerabilities in Africa

Human vulnerabilities that are present in developed countries are often exacerbated in developing countries, due to a wide range of factors, including extreme poverty. This is especially visible in the case of developing countries of sub-Saharan Africa. The Committee has consistently maintained this concern within its reflection on Article 8. This is particularly evident with the mention of three specific cases from Africa, even though the general practice is to remove specific regional or national references. Other cases highlight vulnerabilities of immediate relevance to the African context, while the remaining cases are applicable to fast emerging situations on the continent. In essence, all the possible remedies elaborated within the Report, from providing vulnerable populations with adequate health education and access to available therapies, to striving against poverty and strictly limiting the use of potentially discriminating incentives in medical research, have universal application across both developed and developing countries, but are especially pertinent to the African context.

Ultimately, the goal of our efforts in this regard is to inspire and stimulate all stakeholders, not only States, to take the necessary steps to protect the interests of vulnerable populations in the context of healthcare, research and the application of emerging technologies in the biomedical sciences; and to ensure the realization and enjoyment of human rights across all strata of society.

Stefano Semplici

Chairperson

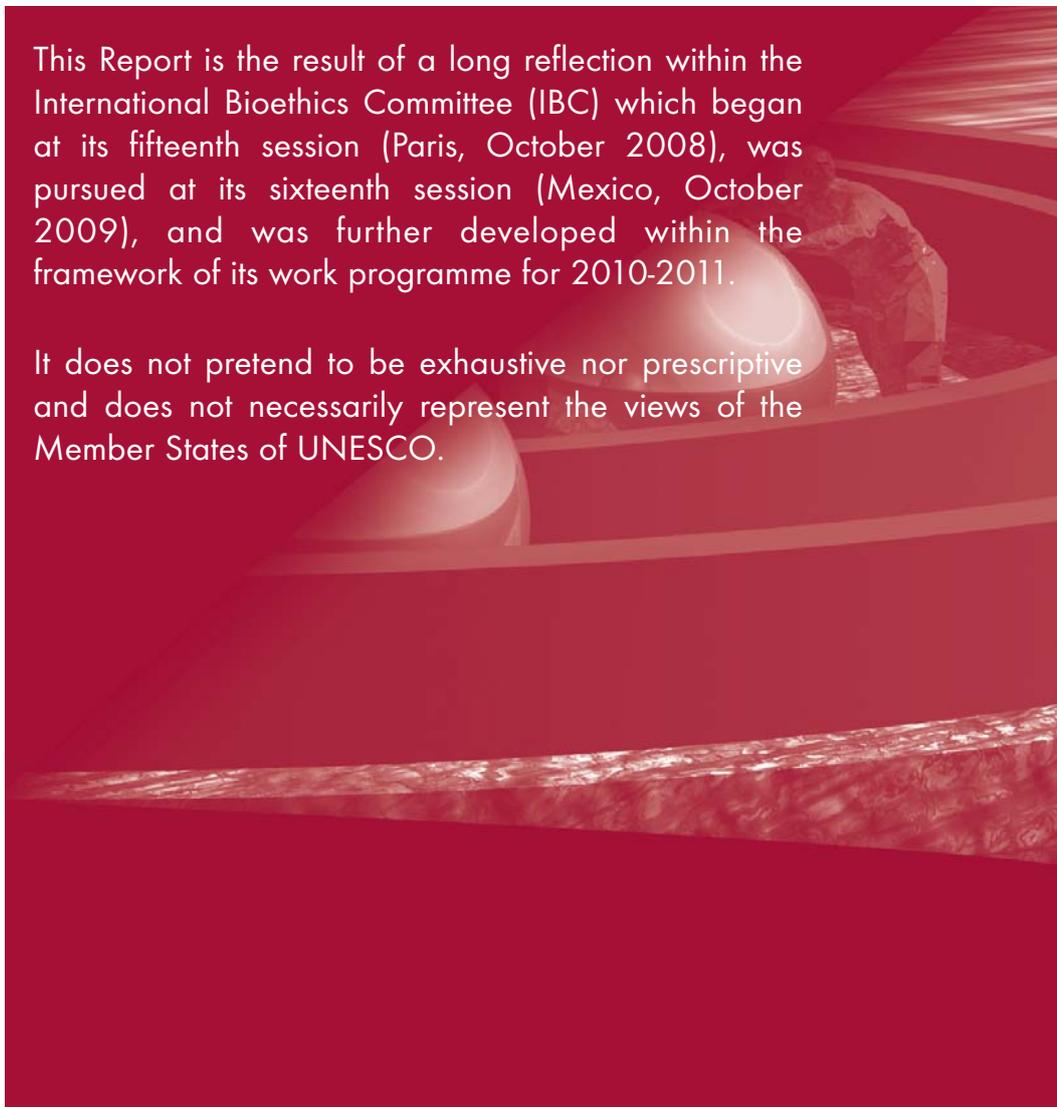
UNESCO's International Bioethics Committee

THE PRINCIPLE OF RESPECT FOR HUMAN VULNERABILITY AND PERSONAL INTEGRITY

Report of the International Bioethics Committee of UNESCO (IBC)

This Report is the result of a long reflection within the International Bioethics Committee (IBC) which began at its fifteenth session (Paris, October 2008), was pursued at its sixteenth session (Mexico, October 2009), and was further developed within the framework of its work programme for 2010-2011.

It does not pretend to be exhaustive nor prescriptive and does not necessarily represent the views of the Member States of UNESCO.



I. INTRODUCTION

1. Article 1 of the UNESCO **Universal Declaration on Bioethics and Human Rights** (2005) (hereafter “the Declaration”) states that it seeks to address the “ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions” (the full text of the Declaration is given in Annex I). Article 8 reinforces this commitment by linking it to respect for personal integrity and the need to protect vulnerable individuals and groups:

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

2. This notion is not new. The concept of vulnerability appears in important national documents, starting with the US Belmont Report of 1978, and in international documents, such as the third and most complete version of the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS) (2002) and in the latest (2008) version of the Declaration of Helsinki, which makes specific reference to vulnerability in articles 9 and 17.

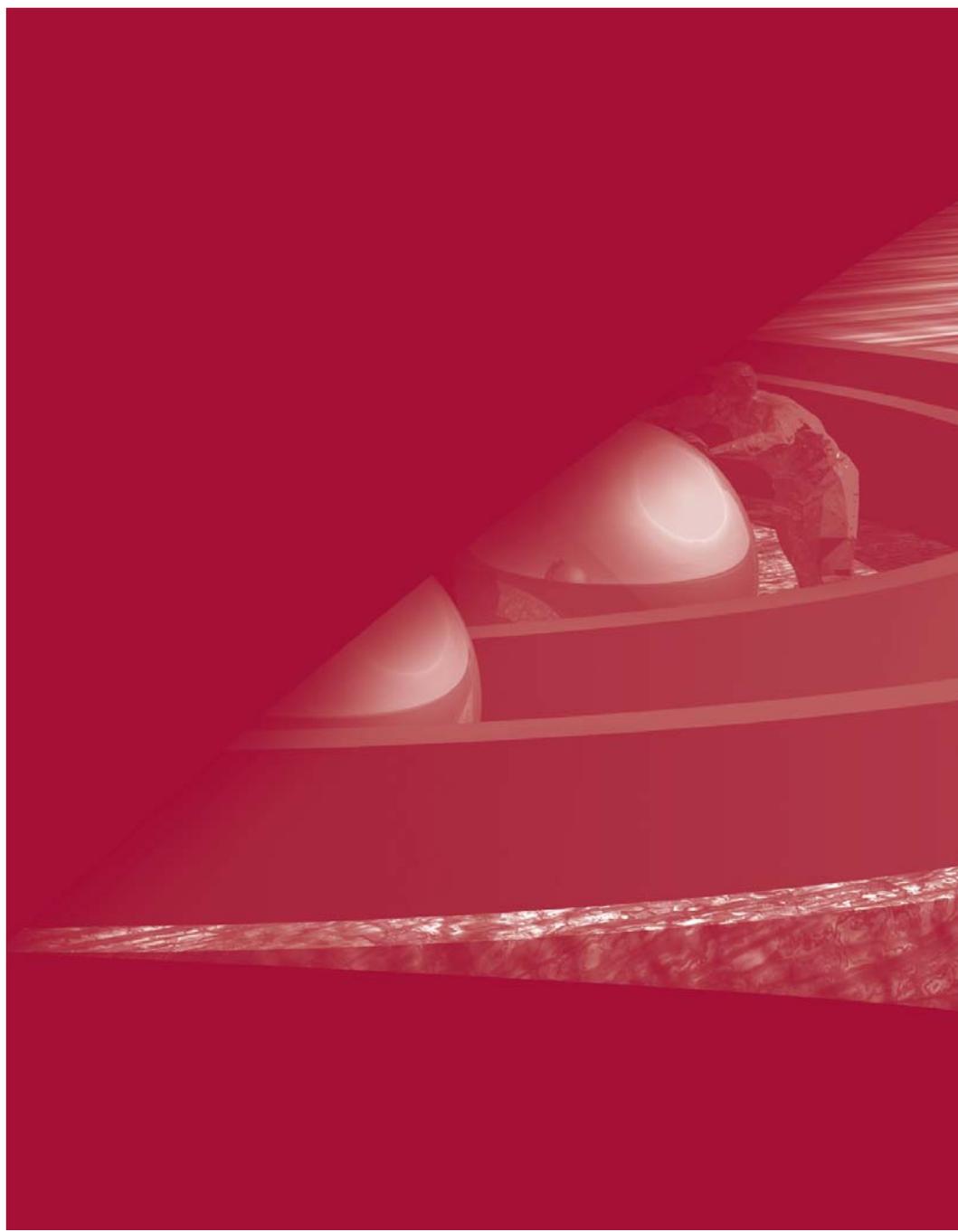
3. Article 8 of the Declaration entails both a ‘negative’ duty to refrain from doing something and a ‘positive’ duty to promote solidarity and to share the benefits of scientific progress. There is an integral relationship between respect for the integrity and dignity of persons on the one hand and the vulnerability of persons on the other. Indeed, UNESCO itself had previously acknowledged the importance of the principle according to which States “should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable” with regard to disease or disability of a genetic character (Universal Declaration on the Human Genome and Human Rights, 1997).

4. The UNESCO International Bioethics Committee (IBC) has focused its two more recent Reports on the principles of consent (Art. 6 of the Declaration) and of social responsibility and health (Art. 14). This Report on article 8 of the Declaration will investigate the scope and content of the principle of respect for human vulnerability and personal integrity, focusing on special vulnerabilities and taking into account conditions that, more or less directly, impinge upon the capacity to live as a free, autonomous individual and the right to live in a world where significant inequalities in the capacity to meet everyone’s basic needs are adequately addressed.

5. Article 1.2 of the Declaration makes it clear that it is addressed to States. However, States and governments are not the only addressees of Article 8. As in the case of the principle of social responsibility, it is rather necessary to boost awareness of the responsibility that all sectors of society share and to promote, at the international as well as the domestic level, those strategies and means of cooperation that are most likely to effectively address the determinants of “special” vulnerability to which Article 8 refers. Of course, both an in-depth reflection on the concept of vulnerability as a general feature of the human condition and denunciation of political, economic or cultural

discrimination among human beings are important. Nonetheless, they constitute the background more than the focal point of the challenge faced in Article 8. The specific task of this Article is to address special vulnerabilities that occur, whether as a consequence of personal disability, environmental burdens or social injustice, in the contexts of health care, research and the application of emerging technologies in the biomedical sciences. Article 8 enjoins everyone to exercise vigilance in protecting the well-being of individuals and groups in these contexts. As the Declaration (taken as a whole) confirms, every human being has a claim to our care that must be respected.

THE DETERMINANTS OF “SPECIAL VULNERABILITY”



II. THE DETERMINANTS OF "SPECIAL VULNERABILITY"

6. The human condition implies vulnerability. Every human being is exposed to the permanent risk of suffering "wounds" to their physical and mental integrity. Vulnerability is an inescapable dimension of the life of individuals and the shaping of human relationships. To take into account human vulnerability acknowledges that we all may lack at some point the ability or the means to protect ourselves, our health and our well-being. We are all confronted with the possibility of disease, disability and environmental risks. At the same time, we live with the possibility that harm, even death, can be caused by other human beings.

7. Of course, article 8 does not require us to protect vulnerability as such, but rather vulnerable individuals, families and groups in the contexts in which they live. While some groups of people can always be considered vulnerable because of their status (e.g. children), others may be vulnerable in one situation but not in another. Therefore, vulnerability cannot be considered as a one-off concept. The principle of respect underpinned in Article 8 entails a commitment to identify threats to well-being and appropriate means to foster the principles stated in Article 3 to be the primary ones "to be respected": human dignity, human rights and fundamental freedoms. Thus, attempts to define vulnerability in general risk drawing the concept too widely or too narrowly, thereby triggering disputes rather than resolving them. In most cases, however, it is relatively easy to recognise vulnerability when it arises: something fundamental is indeed at stake.

8. That is also why human vulnerability and personal integrity, the other essential concept evoked in Article 8, relate to each other. When a part of our body is inappropriately 'touched' (this is the meaning of the ancient Latin verb from which the noun 'integrity' stems), our life itself, or at least our health, may be threatened. When our freedom is hampered, either by adverse circumstances or by the actions of others, we experience a "wound" to our identity, to its value and dignity. Preservation of integrity implies protection against these kinds of intrusions, the capacity to "say no" to any sort of impingement upon our freedom or to any sort of exploitation of our body and our environment. We are nonetheless committed at least to seek to ameliorate the effects of harms and disadvantages imposed by circumstances. This is a prerequisite of human flourishing and self-fulfilment.

9. The Declaration, taken as a whole, enjoins governments, but also public and private institutions and individuals, to exercise greater vigilance in protecting the well-being of every human being in the face of advances in the fields of medicine, life sciences and associated technologies. By doing so, it underscores the importance of a wide array of principles familiar to the language of both moral and juridical sciences: autonomy, beneficence, justice, dignity, equality and the like. The principle of respect for vulnerability and personal integrity not only emphasises these aims, but also clarifies that the final goal of the progress of science in the bioethical domain cannot solely be profit. Vulnerability as a human condition calls on every human being, especially those who have the responsibility to advance knowledge and to decide how to use it, to fulfil the fundamental obligations we have one to another. It has been said that acknowledging the reality of vulnerability might provide a bridge between the moral 'strangers' of a pluralistic society, thereby enhancing the value of solidarity rather than mere individual interests.

10. At the same time, Article 8 clarifies that we cannot be satisfied with the simple exercise of restraint and forbearance in pursuing our own objectives when this might threaten the autonomy and dignity of others. We are compelled to act in a positive way to help other people cope with the natural or social determinants of vulnerability. Article 24 underscores the duty to “respect and promote solidarity between and among States” and points out some circumstances that may render individuals, families and groups vulnerable: disease; disability; other personal, societal or environmental conditions or limited resources. There is no doubt that the empowerment of people to protect them from special vulnerabilities in health care entails making more resources available, providing safe living conditions and access to quality health care as a precondition to every human being’s “enjoyment of the highest attainable standard of health” (Art. 14 of the Declaration). In this sense, commitment to respect for human vulnerability and personal integrity is a necessary constituent of unavoidable political responsibilities.

11. Humankind as such is vulnerable, but there are individuals, groups and situations to which a greater attention must be paid. This is the essential point to underline. Article 8 explicitly addresses the “special vulnerability” of individuals and groups, inasmuch as they are potential recipients of therapies, involved in scientific research or potential recipients of the products or technologies deriving from the advancement and applications of scientific knowledge. Of course, this is not the only context in which vulnerability occurs. Human dignity, human rights and fundamental freedoms are equally at stake in many other fields of human activity. They are, however, relevant to the scope of the Declaration only insofar as they overlap with the specific tasks of bioethics and medical ethics.

12. Two fundamental categories are highlighted that are relevant to these special responsibilities and obligations:

- a)** special (temporary or permanent) disabilities, disease and limitations imposed by the stages of human life;
- b)** social, political and environmental determinants: for example culture, economy, relations of power, natural disasters.

13. In a) for example, children are assumed to be vulnerable regardless of their social conditions. Elderly people may be more vulnerable because of their reduced physical and sometimes mental capacities. Persons with disabilities need help to access and sustain the exercise of their self-determination. Persons with mental disorders may not be able to defend themselves or claim their rights. These can all be considered as “natural” determinants of special *individual* vulnerabilities. Of course, a crucial distinction is to be made between these and special vulnerabilities which result from a deliberate restriction of autonomy.

14. The issue of social, political and environmental determinants is more complex and involves the fundamental matter of justice in the relations between individuals, groups and States. Many individuals, groups and populations nowadays become especially vulnerable because of factors created and implemented by other human beings, in many cases in blatant violation of fundamental human rights. Social vulnerability is a phenomenon determined by the structure of people’s and communities’ daily lives. Situations of social vulnerability usually interfere with the self-determination of individuals and lead to significantly increased exposure to risks caused by social exclusion. Social vulnerability plays a role not only in biomedical research but also in the healthcare setting and in the development, implementation and application of emerging technologies in biomedical sciences and is a fact of life for a considerable portion of world’s

population. Vulnerability is caused or exacerbated by a lack of means and of the capacity to protect oneself, as in the following examples:

- poverty, inequalities in income, social conditions, education and access to information (e.g. unemployed persons, homeless persons, illiterate persons, individuals involved in research activities that follow a 'double standard' procedure in which the same research is not subjected to the same ethical scrutiny in different locations);
- gender discrimination (e.g. lack of equitable access to healthcare);
- situations of substantial limitation or deprivation of personal liberty (e.g. prisoners);
- hierarchical relations (e.g. students involved in research projects carried out by their teachers, employees in situations where safe working conditions are not guaranteed, members of the armed forces or the police);
- marginalization on various grounds (e.g. immigrants, nomads, ethnic and racial minorities);
- trade-offs between the right of every human being to quality health care and other rights, such as intellectual property rights, whose inappropriate protection can directly or indirectly impinge negatively upon the sharing of the benefits of scientific progress;
- exploitation of resources in developing countries (e.g. the consequences of deforestation which can compromise duties towards future generations);
- wars (e.g. asylum seekers and displaced persons);
- negative effects of human activity, for example climate change or different kinds of pollution;
- impact of natural disasters like earthquakes, hurricanes or tsunamis leading to death, injury and displacement.

15. All of these examples help contextualize the issue of vulnerability and respect for personal integrity within the three specific domains pointed out in Article 8. They serve to highlight the issues in the healthcare setting, in the researcher-participant relationship in human participant research, and in the development and application of emerging technologies in the biomedical sciences. In each of these settings people are vulnerable in ways over and above that which the human condition necessarily involves.

16. As to vulnerability in the healthcare setting, it is well understood that even those patients whose physical and cognitive capacities meet or exceed those of the average human population are uniquely vulnerable when submitting to medical care, given the greater expertise and social authority of the treating physician (and other professionals). A patient's vulnerability may be further aggravated by his or her illness – pain, discomfort and the desire for healing can frustrate reasoning and sound judgment. This is a fortiori true of those patients whose physical or cognitive abilities are severely diminished such that their capacity for self-determination is limited or even non-existent. In all healthcare settings, the patient, to a greater or lesser degree, depends on the skills, expertise, judgment and good will of the treating professional. Individually and collectively, patients are thereby uniquely vulnerable. Article 8 calls our attention to this fact and enjoins decision makers to respond in a fitting way. One possible option would be for States to develop a patients' rights charter which would be instrumental in protecting those who are especially vulnerable in the healthcare setting.

17. The same is true of human participants in biomedical research. However, in this context, the additional safeguard of the physician's (or researcher's) primary focus being on restoring the patient to health is absent. The interests of researchers and subjects are not always aligned as they are in the relationship between healthcare professionals and patients, thus amplifying concerns regarding vulnerability in this domain. Moreover, in some instances, the researcher's (or society's)

understandably strong desire to pursue useful generalisable knowledge gives rise to the temptation to under-protect or ignore the participants' wellbeing. The Declaration's emphasis on special vulnerability rightly invites careful attention to this and related concerns in the human research context. It is clear, however, that the engagement of people as participants in clinical research is key in providing solutions to, and understanding of, medical problems afflicting humankind. Biomedical research, including clinical research, has evolved over the years to the extent that international and national standards and guidelines have been developed. The practices uncovered at the Nuremberg trials showed the range and extent of the abuse of human beings in research and resulted in a flurry of activity on this subject. The resulting Nuremberg Code⁽¹⁾ the template for a number of successive declarations on human participant research, culminating in the World Medical Association's Declaration of Helsinki, which states that:

Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.⁽²⁾

18. Equally, some individuals or communities may be denied access to, or the benefits of, research. They too are especially vulnerable.

19. It is especially important in all forms of research that close attention is paid to the kinds of pressures that might encourage people to act in a manner that potentially competes with their own interests; in particular, the avoidance of coercion or of the appearance of coercion is vital. Coercion may arise from a number of sources, including the simple omission of relevant information about possible risk. As research is often conducted by investigators from the developed world in countries of the developing world, a number of concerns arise acutely. First, the personal, economic or socio-political situation of potential research participants may render them vulnerable to exploitation. Second, again because of the so-called 'therapeutic misconception', people may agree to participate in research in the mistaken belief that there may be some benefit for them; this is particularly likely where healthcare services are inadequate or unavailable. CIOMS' most recent guidelines note that, special justification is required for inviting vulnerable individuals to serve as research participants and, if they are selected, the means of protecting their rights and welfare must be strictly applied.⁽³⁾

20. Advances in biomedical science and biotechnology have opened the way for many new and powerful capacities for the protection of human welfare. At the same time, they have created novel and potent mechanisms of exploitation and degradation. Such advances potentially give rise to a special vulnerability for individuals and groups to which Article 8 rightly draws our attention.

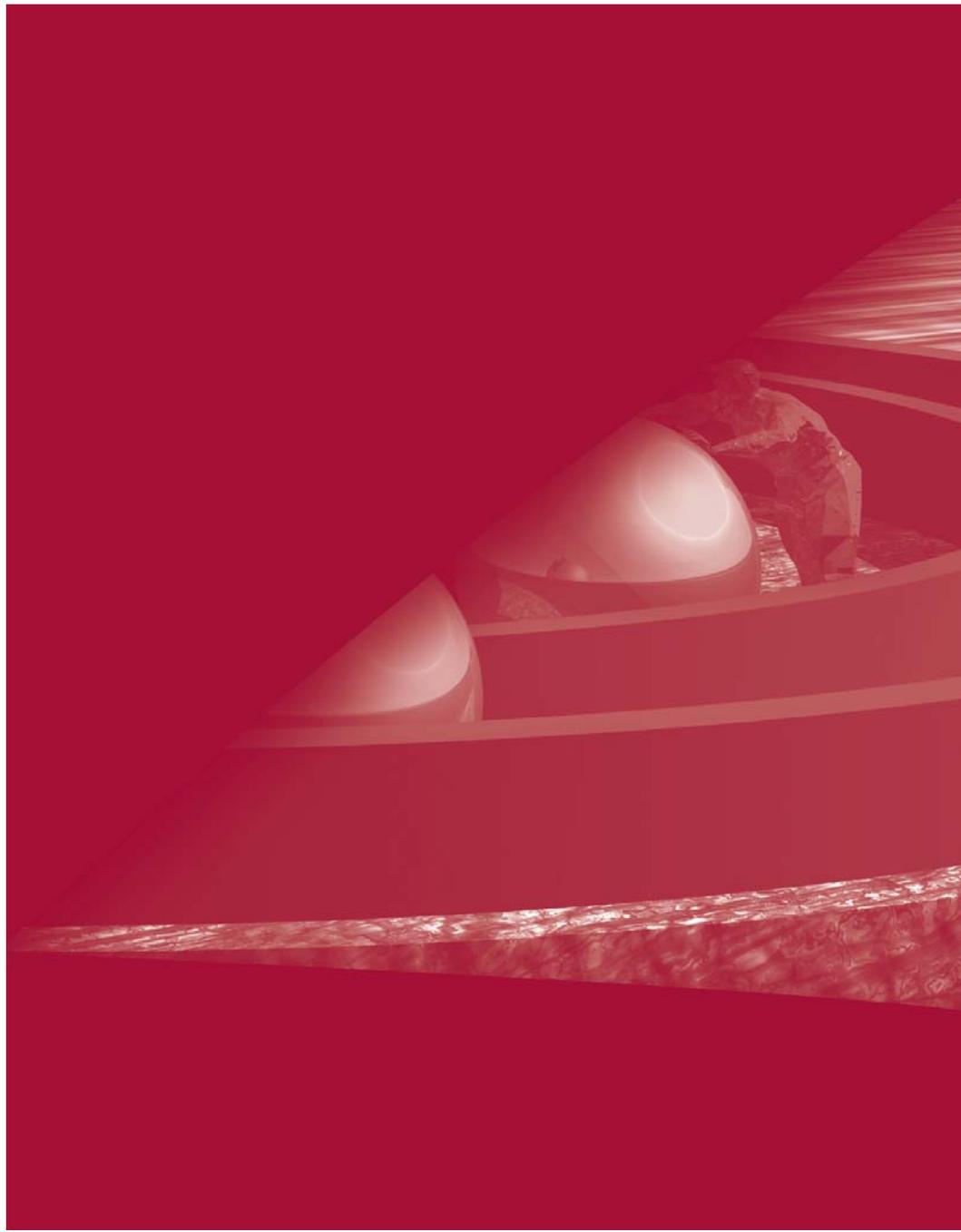
21. Each of these contexts presents instances where individuals and groups may be vulnerable in a unique and amplified form. A number of examples follow which illuminate some situations within healthcare, human participant research and the development of biotechnology which give rise to "special vulnerability". It is, of course, not intended that these examples are exhaustive of situations where vulnerability can be identified; rather, they are illustrative.

(1) Available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html> (accessed 03/08/2010).

(2) Declaration of Helsinki, article 9. Most recently revised at the 59th WMA General Assembly, Seoul, October 2008.

(3) For discussion, see Macrae, D.J., 'The Council for International Organizations and Medical Sciences (CIOMS) Guidelines on Ethics of Clinical Trials', *Proc. Am. Thorac. Soc.* Vol. 4, 176-179, 2007.

VULNERABILITY IN THE HEALTHCARE SETTING



III. VULNERABILITY IN THE HEALTHCARE SETTING

III.1. Access to healthcare

III.1.1. Poor people in developing countries

22. According to the Joint United Nations Program on HIV/AIDS (UNAIDS) in its 2008 report⁽⁴⁾, by the end of 2007, 33.2 million people were living with HIV, of whom 2.1 million were children, and 2.1 million died from AIDS. Some 6,800 people are newly infected with HIV every day because of poor access to affordable, proven interventions to prevent HIV transmission. Only 2700 people receive antiretroviral therapy per day. Only 31% of people in need were receiving antiretroviral therapy in 2007, and only one third of infected pregnant women receive antiretroviral drugs to prevent transmission; even fewer receive medications for their own health.

The nature of the vulnerability

A shortened life of poor quality and the risk of imminent death.

The cause or context of the vulnerability

The inability or failure of States to purchase adequate supplies of existing and effective drugs, coupled with the inadequate promulgation of preventive strategies.

Remedies

States to intervene directly by providing adequate health education and access to available therapies. International solidarity to be encouraged to facilitate such provision.

III.1.2. Disadvantaged people in developed countries

23. A 24 year old female with a history of headaches consulted a physician for treatment. Following the initial diagnosis, it became clear that advanced diagnostic tests were required, but these tests were expensive and not covered by her insurance. Under these circumstances, the tests were not offered. A few months later, further examination revealed an advanced cerebral tumor, which had a poor prognosis.

The nature of the vulnerability

Lack of access to diagnostic tests which fatally delayed possible life-saving treatment.

The cause or context of the vulnerability

Advanced diagnostic tests could have permitted an early diagnosis, which might have given the patient a better prognosis. However, tests or therapies that patients are unable to pay for, either directly or by insurance, are not made available by the healthcare system. Patients are, therefore, not always informed about alternative techniques and therapies.

Remedies

The availability of appropriate healthcare resources to meet the needs of the patient population irrespective of ability to pay, and the requirement that full information is available to patients about alternative diagnostic or therapeutic opportunities.

(4) Available at www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008 (accessed on 02/08/2010).

II.1.3. Migrants

24. P. was a young pregnant woman who was an immigrant in a country which provides free access to quality health care for all its citizens. During her pregnancy, she did not seek ante-natal care and was never visited by a doctor. At the moment of delivery, her husband took her to the hospital, but the newborn immediately needed intensive care and ventilation. The child was premature and its birth weight was extremely low compared with children of the same gestational age. P. suffered serious kidney and liver problems that required lengthy treatment. A survey carried out in the hospital showed that this sort of complication and the rate of in-hospital mortality were significantly higher in the case of babies born to immigrant women. These rates appeared to be related to risk factors which could be easily prevented by routine testing during pregnancy.

The nature of the vulnerability

Migrants may not be aware whether or not they have a right to treatment. They may also be unaware of the range of tests and therapies available, and may be impaired in their ability to seek access to care.

The cause or context of the vulnerability

Migrants in general, whether within or between States, may find themselves marginalized, because of a lack of knowledge of local language and social and legal entitlements.

Remedies

Thorough social integration of migrant individuals and communities into the mainstream, better and more targeted education about healthcare risks and ease of access to healthcare professionals.

III.2. Provision of appropriate healthcare

III.2.1. Paediatric HIV infection

25. Antiretroviral therapy (ART) coverage of all age groups in sub-Saharan Africa was 44% in 2008, compared to 33% in 2007. However, only 5–7% of those receiving treatment were children. Out of 22 antiretroviral drugs approved and available for use in adults, 6 have no paediatric indication and 7 have no paediatric formulation.

The nature of the vulnerability

The high risk of infection leading to an early death, as well as the inappropriate use of drugs not tested upon children or not suitable for them. The health and wellbeing of children are threatened by being potential recipients of therapies that are not formulated for them and where the data on toxicities is limited.

The cause or context of the vulnerability

The lack of paediatric formulation for the treatment of HIV/AIDS means that children are administered crushed drugs or those in powder form which need to be reconstituted with clean drinking water. In resource poor settings clean water may not be available, leading to additional problems such as infections, diarrhoea and vomiting. In addition, children are not mini-adults, and it is important that ethically sound research into the development of paediatric therapies is conducted. A lack of appropriate care and education during pregnancy and childbirth, as well as the absence of alternatives to breast feeding for many HIV positive women, conspire to spread HIV to future generations.

Remedies

The provision of targeted educational programmes for women, coupled with the availability of appropriate medication suitable for paediatric use.

III.2.2. Unfair allocation of resources

26. A 73 year old diabetic patient was admitted to hospital with obstructive vascular disease and necrosis of his right foot. The amputation of his right leg was indicated. The surgery was scheduled on a number of occasions but was postponed due to a shortage of resources and because of his age. He remained hospitalized for 5 months, and his leg was never amputated. Finally, he succumbed to sepsis and died, despite the fact that the amputation could have saved his life.

The nature of the vulnerability

The patient was more vulnerable to death because of the policy to discriminate against older patients when allocating scarce resources.

The cause or context of the vulnerability

The increase in healthcare costs reduces the opportunities for many patients to receive appropriate treatment. While more and more technologies are available, they are used on fewer patients because of associated costs. The uneven availability of medical treatment occurs even in developed countries, but has even more dramatic dimensions in developing countries.

Remedies

States should have in place a robustly resourced healthcare system that fairly and without discrimination provides adequate care to all citizens.

III.3. Inequality of power in healthcare

III.3.1. Disrespect for the patient's will

27. A 78 year old man with terminal lung cancer was admitted at the emergency room because of respiratory failure. The medical exam and x-rays showed evidence of respiratory infection. The patient was transferred to the Intensive Care Unit (ICU). He asked for a no intubation order. When the doctor talked to the patient's family, to explain to them that the patient would probably need intubation, the patient's daughters challenged their father's wishes because of their religious beliefs. A few hours later, the patient had severe respiratory failure, but he refused to be intubated. Minutes later he fell into a coma, was intubated and connected to mechanical ventilation. The next day he underwent dialysis. During the next 20 days, he continued to be intubated, underwent dialysis, received antibiotics, mechanical ventilation and hemodynamic support, until he finally died.

The nature of the vulnerability

The clear wishes of the patient were disregarded and his autonomy was thus disrespected. There is no suggestion in the case that his autonomy was impaired at the time he made his wishes clear.

The cause or context of the vulnerability

The principle of informed consent is at risk whenever someone claims to know what is the right thing to do, and insists that his or her decision should prevail over the self-determination of the patient, whether that person is the physician or a family member. In this case, the precarious condition of the patient alone cannot justify overriding his wishes but the dire consequences of not intubating and the pressure from the family serve to undermine respect for patient autonomy.

Remedies

Reinforcement of the need to protect an individual patient's integrity, including specifically the importance of respecting the right to refuse treatment. Appropriate clarification of the legal relevance

of the views of relatives of incompetent patients should be provided to healthcare professionals as part of their professional education.

III.3.2. Professional self-interest

28. A doctor devises a treatment which he/she believes is likely to be beneficial, and advertises and offers it to many patients, without disclosing that he/she stands to benefit financially and that the procedure has not been satisfactorily tested.

The nature of the vulnerability

The vulnerability is to financial exploitation and potential physical harms.

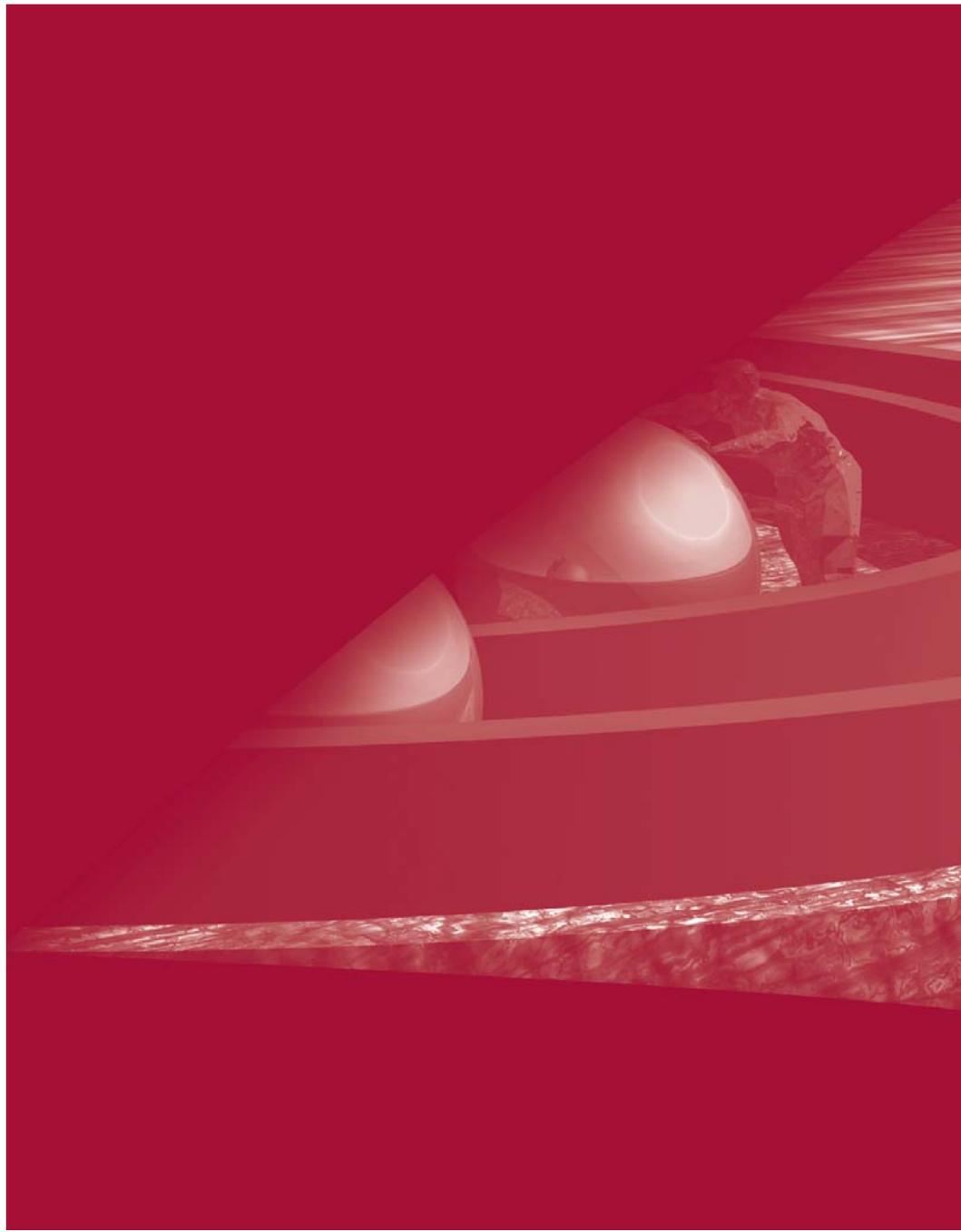
The cause or context of the vulnerability

The inequalities in the doctor-patient relationship, the relationship between the expert helper and the needy patient, made the patients vulnerable to exploitation and harm as a result of the powerful combination of the attractiveness of the promised outcomes and the perceived authority of the caring doctor.

Remedies

The creation and enforcement of safety controls for medicines and medical devices and insistence on independent ethical review of innovative treatments, including the use of medical devices.

VULNERABILITY IN HUMAN PARTICIPANT RESEARCH



IV.1. 'Double Standard' research

29. The proposal was made that a new vaccine be tested on citizens of a developing country where the targeted disease had reached epidemic proportions. The proposal failed to pass the scrutiny of ethical review committees in the country of origin on the grounds of safety. The justification for moving the application to the needy country was said to be that the extra risks for participants could be justified by the pressing needs of their country's population. In addition, the research institutions in the targeted communities were offered significant financial incentives to participate.

The nature of the vulnerability

The vulnerability was to the loss of individual dignity, the risk of exploitation and threats to wellbeing. In addition, it is unlikely that the residents of this poor country would be able to afford access to the vaccine should it prove efficacious.

The cause or context of the vulnerability

The needs of the target population could be argued to be almost overwhelming. However, they also created a powerful temptation to overlook the needs of a small number of individuals who might potentially become infected as participants in the study, given that these vaccines have the potential to cause infection with the target disease and that safety was the issue which caused the body reviewing the ethics of the research protocol not to approve the clinical trial. This increase in vulnerability to the harm caused by the disease in the name of the public good was a threat to their dignity and autonomy as individuals. Moreover, there was reason to doubt that the research could be ethically justified. Additionally, the handsome rewards offered to the research institutions which were in desperate need of funds encouraged researchers to sacrifice the interests of individual participants to the interests of society, in direct opposition to a fundamental rule of medical research.

Remedies

Insistence that research protocols be approved both by independent ethics committees in the country of origin of the research and in the country where the research is to be executed. In the absence of ethical review networks in the country of the research, companies should actively support the creation of such facilities before making proposals to carry out research in the area in question. Moreover, there should be a guarantee that the benefits derived from such research will be shared with the research population.

IV.2. Equivocal donations

30. A gift of much needed antibiotics was made to a country torn by civil war, as part of an international aid package in the form of a drug which has not been fully tested or licensed. The gift was dependent on an agreement by the doctors administering the drug to monitor the use and outcomes of the drug and report results back to the donor.

The nature of the vulnerability

The nature of the vulnerability is to exploitation and possible harm to health.

The cause or context of the vulnerability

The desperate shortage of antibiotics and the extreme needs of the population made the improper offer attractive to the potential recipients. The potential harm results from the lack of transparency of the donation and pressure on potential recipients – even if they were informed of the condition of the gift – to take risks that they would likely, in normal circumstances, be unwilling to take. The subterfuge in fact avoided the disclosure of risks and the necessity of obtaining consent to participate in research rather than medical treatment.

Remedies

The creation and enforcement of strict international controls over the export of medicines from donor countries, with special vigilance in emergency situations.

IV.3. Inappropriate research

31. Drug company A, a large multinational company, initiated a human participant ‘trial’ whose purported aim was to evaluate the relative efficacy of its own product in relation to similar drugs produced by companies B and C. The trial – which was conducted by eminent doctors in highly regarded academic institutions and who received significant financial benefit – purportedly established that the drug was indeed more efficacious than those of the other companies. However, analysis of the published results subsequently showed that the trial design was flawed in such a way that it was not unbiased.

The nature of the vulnerability

Participants were exposed to unnecessary risks and were not provided with honest and accurate information about the purpose of the ‘trial’. Their autonomy and wellbeing were at risk. The fact that eminent doctors and institutions were involved resulted in patients ‘volunteering’ for something in which they might otherwise have declined to participate.

The context and cause of the vulnerability

The ‘trial’ was inherently flawed and arguably entirely unnecessary, and it was, in fact, little more than a marketing exercise.

Remedies

Enhanced regulatory control of clinical trials of medicinal products and improved scientific and ethical review of such proposals.

IV.4. Social vulnerability

32. A woman of African origin, 45 years old and resident in a poor neighbourhood in a big city of a developing country, had recently been abandoned by her husband. She was the mother of six children, living in poverty. Her 4 year old son was unwell, with a possible diagnosis of acute glomerulonephritis. Overcrowding at the hospital meant that her son had yet to be seen by a doctor after one full day of waiting; she was eventually informed that her son would be entitled to receive the necessary interventions if she would participate in a clinical trial being developed at the hospital. She would be required to take two tablets of a new anti-inflammatory drug, daily, for 15 days. She agreed to participate in return for the treatment her son needed.

The nature of the vulnerability

The woman's autonomy was at risk as her ability to provide a valid consent was in doubt, given her concerns for her son's health. She was also vulnerable to any risks involved in the trial.

The cause or context of the vulnerability

Situations of social vulnerability often interfere with the power of self-determination of individuals and lead to significantly increased exposure to a variety of risks. Some of the contextual factors that generate social vulnerability in biomedical research are: poverty and low educational level among the population; difficulty in accessing healthcare; being female; marginalised racial and ethnic background; low capacity for research in a country.

Remedies

The alleviation of poverty and strict limitations on the use of potentially coercive incentives to participate in research.

IV.5. Vulnerability as a result of lack of research

33. A group of diseases, known as Neglected Tropical Diseases (NTDs), are parasitic and bacterial tropical diseases that primarily affect the most impoverished and vulnerable populations in the world. Pharmaceutical companies show little interest in their treatment and eradication as research and development costs are likely to exceed or reduce profit.

The nature of the vulnerability

The vulnerability is to potential physical harm and discrimination as to the right of every human being to the highest attainable standard of health.

The cause or context of the vulnerability

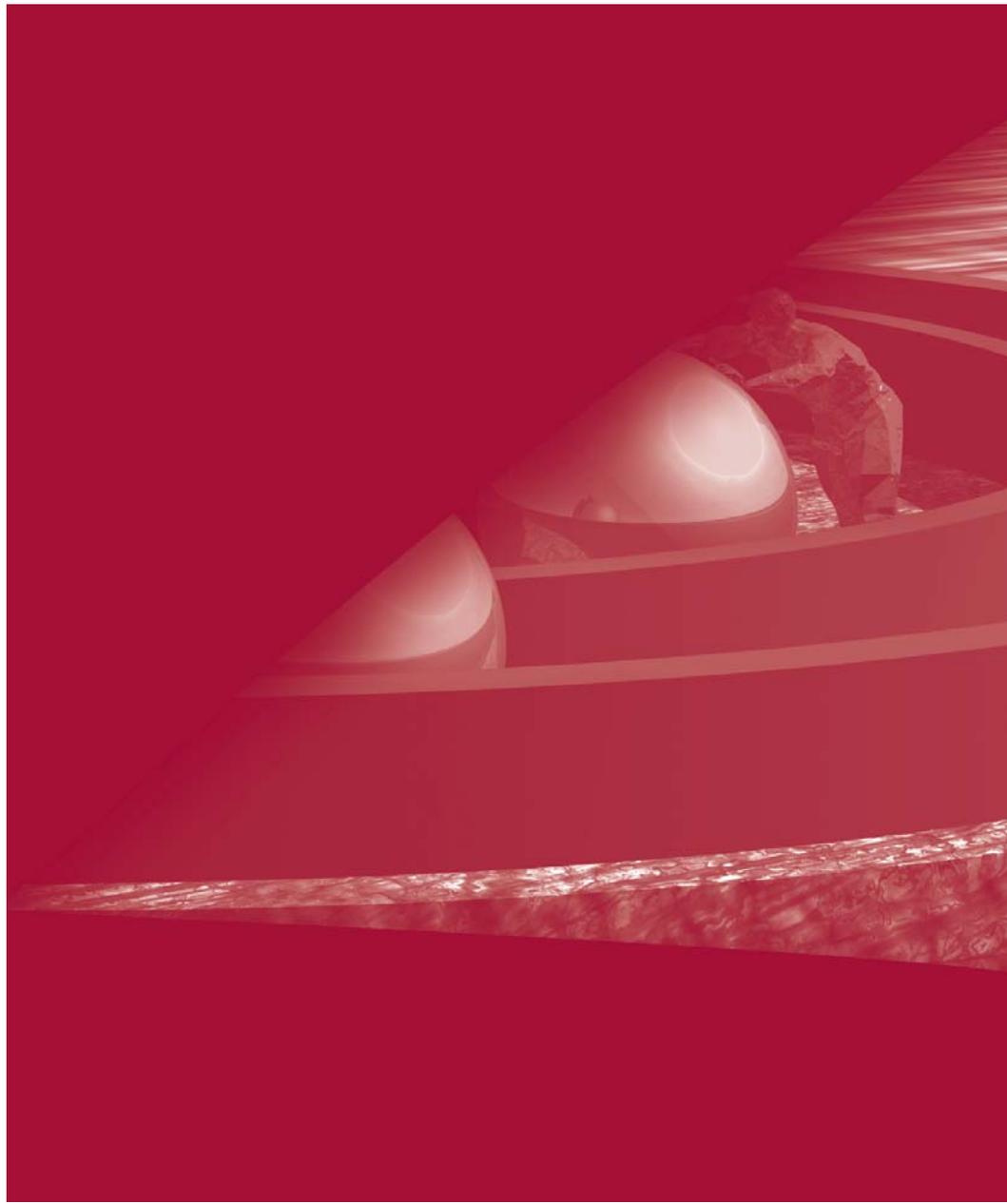
People suffering from NTDs are usually poor and lack access to quality health care and essential medicines. Pharmaceutical industries have failed to invest in the necessary research and development to produce treatment for these conditions.

Remedies

Recognition of the right of all peoples to benefit from scientific advances and its applications is fundamental. Global corporations should be encouraged by the international community and national governments to engage in 'public good' research. If research were conducted and resulted in appropriate treatment for these conditions, the treatment must be affordable for the populations of the countries where these conditions are endemic.

Moreover, particular attention should be paid to the special vulnerability of the groups who would be the subjects of this research. This would require a robust infrastructure to protect people from exploitation or harm. Governments should take responsibility for their citizens by developing policies that give priority to vulnerable communities with the aim of improving their quality of life.

VULNERABILITY IN THE DEVELOPMENT AND APPLICATION OF EMERGING TECHNOLOGIES IN THE BIOMEDICAL SCIENCES



VULNERABILITY IN THE DEVELOPMENT AND APPLICATION OF EMERGING TECHNOLOGIES IN THE BIOMEDICAL SCIENCES

V.1. Stigmatisation

34. A research study using DNA genetic technologies was conducted on a specific ethnic community, whose members were informed that the research was part of a study of cigarette use. A mutation was discovered which had been suggested in the literature possibly to indicate a tendency to criminality and violence. The researcher intuitively linked the finding to the higher representation of members of this group in the country's prisons. This was not the purpose of the research to which the community concerned had consented, but the press took up the 'finding' with enthusiasm. The result was an unsubstantiated claim against this group which was socially damaging and offensive.

The nature of the vulnerability

The vulnerability was to the stigmatisation, victimisation and social discrimination of all members of the group.

The context and cause of the vulnerability

The research 'findings' were foreign to the objectives of the research in which the participants had agreed to participate. No permissions had been sought to amend the research protocol. In addition, the conclusions drawn showed a misunderstanding of the nature of genetic susceptibilities, and drew conclusions that were not substantiated by the research itself.

Remedies

Regulations should be established that require proper consultation with social groups of participants rather than simply with individual participants in the preparation of protocols for studies where knowledge about the group as a whole is sought. The objectives of such studies should be clearly agreed in the consent procedure. Any amendments to the protocol should be reconsidered by the group or its representatives and specific consent sought.

V.2. Unfair pressure

35. Because of a shortage of volunteers prepared to provide oocytes to a clinic's authorized assisted reproduction programme, a scheme was devised to recruit 'volunteers' by offering free access to IVF cycles on condition that the woman agreed that her surplus oocytes would be donated for the treatment of other infertile women. This free service is offered in return for undergoing one procedure of ovarian hyperstimulation, and the harvesting of resultant oocytes for use in the treatment of infertile women who are clients of the clinic.

Nature of the vulnerability

The vulnerability is the threat to the autonomy and wellbeing of the 'volunteers'.

The cause and context of the vulnerability

The offer of a reward in kind to these needy patients put them under considerable pressure to do what most women who have no such needs would not contemplate doing (vide the shortage of donors). They were singled out as a group who were likely to have a weakened resistance to the proposal because of their infertility. In addition, in some cases the incentive to participate was exacerbated by the women's inability to pay for IVF treatment which would otherwise be unavailable to them.

Remedies

Regulations to provide for ethical review of all clinical interventions offered with no promise or expectation of clinical benefit to the patient, including stricter licensing, oversight, monitoring and evaluation of clinics offering these services.

V.3. Premature applications of technology

36. A new sunscreen advertised its superior effectiveness in protecting against UV rays by describing the product as microfine. The description referred to the nanoparticles of Zinc Oxide in the cream. Nanoparticles have been demonstrated to have heightened and powerful properties compared with the normal inorganic particles of materials. However they have also been shown to be capable of penetrating cells, crossing the blood brain barrier and producing serious lipid and protein damage. Yet the cream was marketed on the basis that it provided greater protection of health than other creams.

Nature of the vulnerability

The lack of information in the beguiling advertisement of the product and the lack of adequate risk assessment of the effect of rubbing millions of particles on to the skin fail to facilitate an autonomous decision to apply the cream and threatens the health of the user while promising to do just the opposite.

The cause and context of the vulnerability

The commercial pressure to recoup research and development costs of a technology and to gain an advantage over rival products corrupts the endeavour to provide better healthcare. Undue haste in marketing products by short circuiting proper risk assessment results in hazards to the health of consumers.

Remedies

Cosmetics should be as strictly assessed for safety as pharmaceutical products. Licensing bodies should be aware that the safe use of materials in their normal inorganic state does not provide an adequate guide to their use in nanoparticulate form.

V.4. Genetic information and patient privacy

37. A woman gave birth to a child with serious genetic abnormalities. The clinical team recognised that she carried a mutation responsible for the condition of the neonate. It was a mutation that was likely to be carried by any sister of hers. On enquiry the team discovered that she had a sister in her early twenties. They sought the patient's permission to contact her and offer a genetic test. The patient refused on the basis that she hated her sister and hoped that she had a similar experience and, further, that she did not want the sister to know about the reason for the child's misfortune.

The nature of the vulnerability

The technology gave rise to two special vulnerabilities in this case. The first was the vulnerability of the

patient to an invasion of her privacy if her genetic health information was revealed to another. The second was the vulnerability of her sister to experience what was now an avoidable health hazard.

The cause and context of the vulnerability

Genetic information is not simply information about the presenting patient but might well be information about biological relatives too. Insofar as this is so, there will be inevitable tensions involved in decisions to share or deny such information to those relatives for whom it might be important for health reasons. This might be described as a tension between the right to know, on the one hand, and the right to privacy on the other.

Remedies

Policies should be developed to aid clinicians in such decision making. This is a difficult task, but one possible criterion for divulging confidential information of this kind without the consent of the patient would be the seriousness of the possible health consequences of leaving the relatives involved in ignorance of the matter. Quite different considerations would apply to the many other threats to privacy engendered by the possession of genetic information. These would include access to the genetic data of patients by researchers, insurance companies, employers and governments. Such disclosures would engender major vulnerabilities to restrictions of civil liberties.

V.5. Unexpected risks

38. X-linked severe combined immune deficiency (X-SCID) is a rare genetic disease where gene therapy (which entails modifying or replacing disease causing genes using genetic engineering techniques) was used in clinical trials. Unfortunately, in some of the children treated, leukaemia developed after 3-6 years. This result was attributed to the retroviral vector used to carry the gene to the cells. Cancer developed in patient groups from different centres that were using the experimental treatment. Protocols had to be redefined after the trials have been suspended.

The nature of the vulnerability

Other effective treatments are not yet available and, while those who enter this kind of trial may otherwise die untreated, the full risks of participation cannot be envisioned.

The cause and context of the vulnerability

In life sciences gene therapy is a new form of therapy with high hopes for genetic diseases. However, patients often enter clinical trials without foreseeable knowledge of the increased risk due to the experimental protocol.

Remedies

A full explanation to those contemplating entering such trials concerning what is, and is not, known about the potential risks of their participation.

V.6. Unconsented collection of genetic data

39. A medical organisation proposed that a programme of community genetic screening be introduced by means of which a complete genetic map of neonates could be produced at birth which would constitute part of their permanent medical record. Such a programme would provide valuable

information for the development of future health policies and health research. It would also make it possible for the owners of the map to benefit rapidly from scientific developments in pharmacogenomics and disease prevention as they came to light.

The nature of the vulnerability

The persons from whom data were collected were unable to consent to the collection and storage of this data when there was no imminent need for that information, thereby undermining their potential future autonomy. While parents are generally permitted to offer consent on behalf of their incapable children, this is usually constrained by the need to consider the best interests of the children in question.

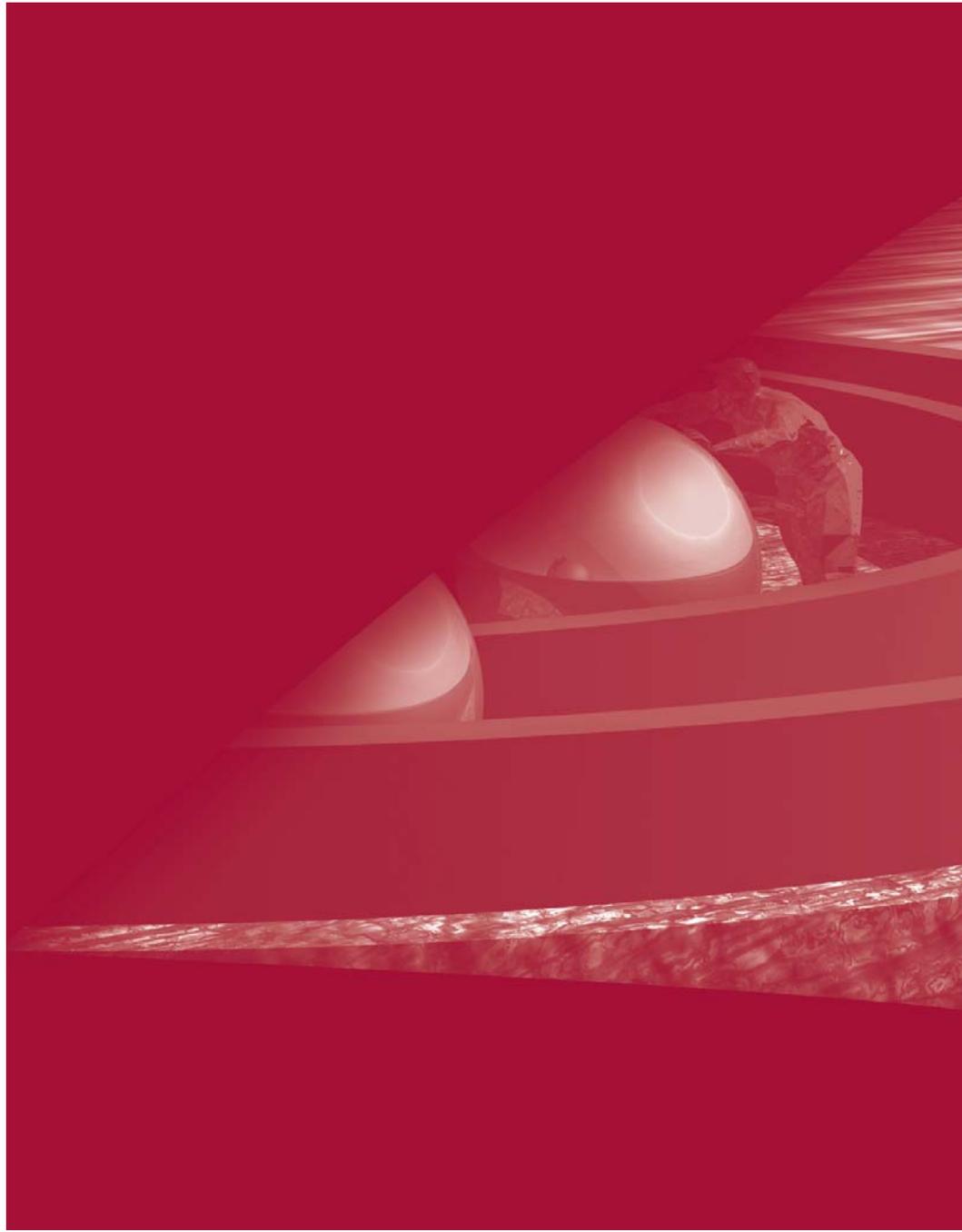
The cause and context of the vulnerability

Knowledge of one's genetic profile can provide diagnostic information about late onset conditions and a growing number of susceptibilities to diseases such as breast cancer. While it might be thought that to be warned of the possibility of developing a serious condition in the future would be an advantage, there are some consequences that need addressing. For example, the potential threat to privacy that arises from the mere holding of this information raises the possibility of discrimination based on genetic profile. In addition, while individuals may wish to know such information, routine neonatal genetic screening makes the right not to know one's genetic status unavailable.

Remedies

Careful consideration of the benefits and drawbacks of collection of such information and the consequences of encouraging parental consent in the absence of the full knowledge of the potential harms. These harms may result either from the fact that the information is recorded, or from the possibility of causing distress to children once they are mature enough to gain access to this information.

CONCLUSIONS



VI. CONCLUSIONS

40. In this report, IBC has provided both a theoretical account of the principle of respect for personal integrity and the need to protect those who are especially vulnerable, as well as a series of practical examples. These examples are not exhaustive of the issues that could be raised; they are rather intended as a useful template for further discussion and development.

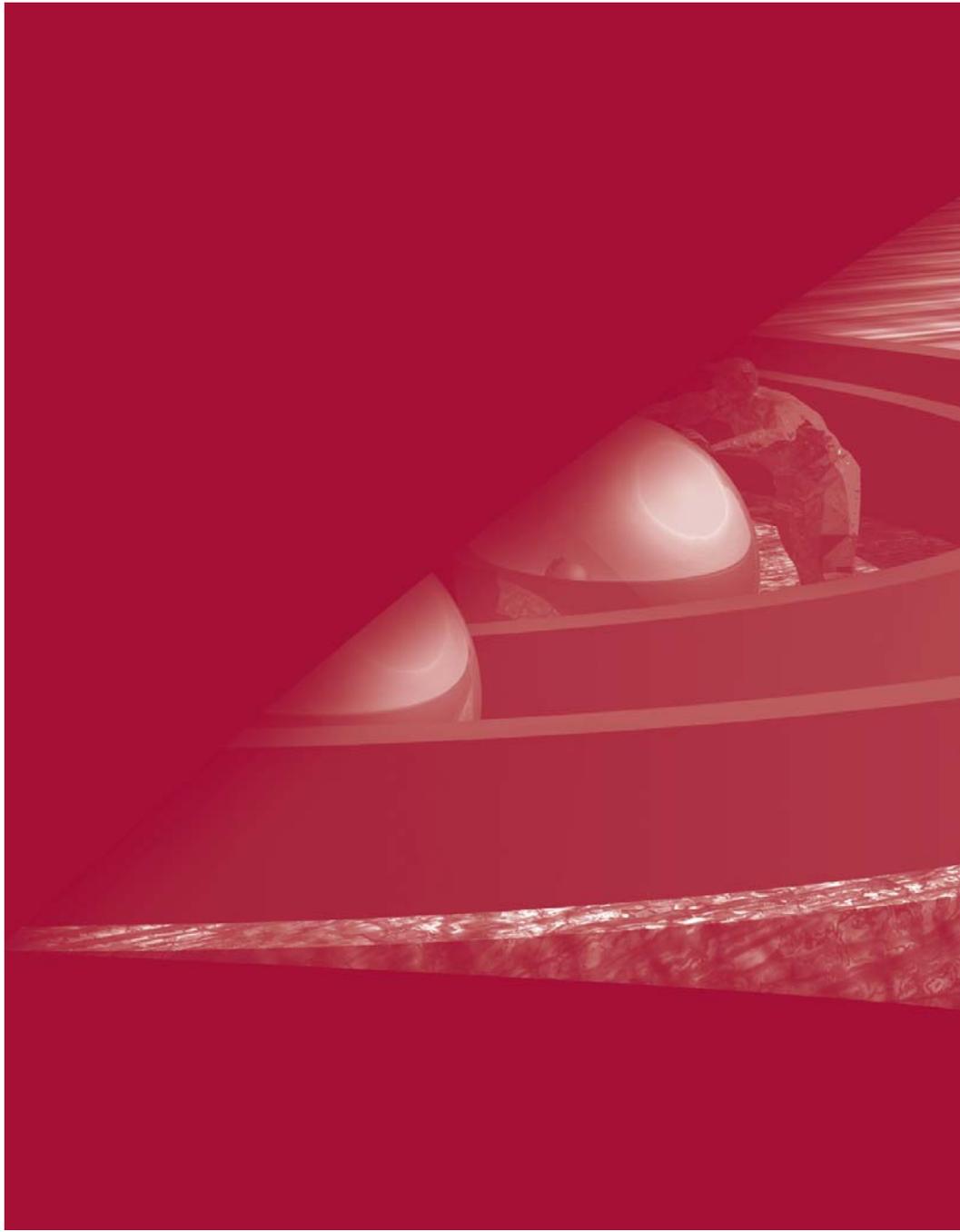
41. Vulnerability as a risk of a human being to be harmed in his or her physical and mental integrity is an element of human condition. Special vulnerability in the scope of Article 8 of the Universal Declaration on Bioethics and Human Rights means that there are individuals and groups that are especially prone to violation of personal integrity or disrespect for autonomy due to exploitation, deception, coercion and disregard through the application and advancing of scientific knowledge, medical practice and associated technologies. People can be especially vulnerable for many reasons: because of their age like children, their kind of disease like rare or neglected diseases, because of lacking access to health care due to the health care system of their country, their own education or the education of physicians and researchers.

42. A further important example of special vulnerabilities can be provided using the example of the position of women. In some cultures, female children are uniquely vulnerable to the risk of being unwanted, uncared for, abused and rejected. Female children may also find their interest in bodily integrity gravely threatened, including especially their right to be free from sexual assault and exploitation. Adult women may find themselves transferred from the patronage of their father to the patronage of their husband, thereby denying them the personal authority to make important life and healthcare decisions on their own behalf. As women live longer in many parts of the world, elderly women might find themselves abandoned by their families, subject to inadequate healthcare, and disregarded by society. Migrant women and women affected by war are especially vulnerable to abuse and are often disenfranchised from engaging in conflict resolution and reconciliation.

43. It must be accepted that situations of vulnerability seldom exist in isolation. Lack of access to education, lack of social authority, limited access to healthcare and freedom from coercion can combine negatively to affect the integrity of people throughout the world. In addition, there are often complex, social, cultural and political barriers that negatively impact on respect for personal integrity, and create seemingly intractable, situations of special vulnerability for both individuals and groups. In particular, lower levels of education always predict higher levels of vulnerability.

44. In its Article 1, the Universal Declaration on Bioethics and Human Rights makes it clear that it is addressed to States, but also to individuals, groups, communities, institutions and corporations, public or private. We all share responsibilities in this area. While we cannot eradicate vulnerability entirely, given that it is a feature of the human condition, we can and should provide every human being with the best available means to ensure that they do not find themselves in a position of special vulnerability, regardless of age, gender, educational level, financial situation, health status and life experiences. Securing the protection of groups and individuals with special vulnerability, by addressing the context and causes that give rise to it, is the foremost test of our capacity and willingness to foster the idea of equal rights and the dignity of every human being.

ANNEXES



UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS⁽¹⁾

The General Conference,

Conscious 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,

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,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving 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 humankind and for the environment,

Recalling the Universal Declaration of Human Rights of 10 December 1948, 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,

Noting the United Nations International Covenant on Economic, Social and Cultural Rights and the International Covenant 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 General Assembly of the United Nations in 1993, the UNESCO Recommendation 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 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 which was adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) annexed to the Marrakech 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),

(1) Adopted by acclamation on 19 October 2005 by the 33rd session of the General Conference of UNESCO.

Also noting 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, which was 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, 1983, 1989, 1996 and 2000 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,

Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law,

Recalling the Constitution of UNESCO adopted on 16 November 1945,

Considering UNESCO's role in identifying 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 generations 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,

Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals,

Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing 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 dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors,

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, is the common heritage of humanity, but emphasizing that it may not be invoked at the expense of human rights and fundamental freedoms,

Also bearing in mind that a person's identity includes biological, psychological, social, cultural and spiritual dimensions,

Recognizing that unethical scientific and technological conduct has had a particular impact on indigenous and local communities,

Convinced that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity, Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities and vulnerable populations,

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,

Proclaims the principles that follow and adopts the present Declaration.

GENERAL PROVISIONS

Article 1 – Scope

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2 – Aims

The aims of this Declaration are:

- (a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;
- (b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;
- (c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;
- (d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;
- (e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;
- (f) 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;
- (g) to safeguard and promote the interests of the present and future generations;
- (h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

PRINCIPLES

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

Article 3 – Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

- (a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;
- (b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same

category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 – Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 – Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to 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.

Article 13 – Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 – Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

- (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;
- (b) access to adequate nutrition and water;
- (c) improvement of living conditions and the environment;
- (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;
- (e) reduction of poverty and illiteracy.

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications 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:

- (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
- (b) access to quality health care;
- (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
- (d) support for health services;
- (e) access to scientific and technological knowledge;
- (f) capacity-building facilities for research purposes;
- (g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.

Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 – Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

APPLICATION OF THE PRINCIPLES

Article 18 – Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19 – Ethics committees

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

- (a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
- (b) provide advice on ethical problems in clinical settings;
- (c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;
- (d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 – Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 – Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.
2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.
3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.
4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.
5. States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.

PROMOTION OF THE DECLARATION

Article 22 – Role of States

1. 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.
2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.

Article 23 – Bioethics education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.
2. States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non governmental organizations in this endeavour.

Article 24 – International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.
2. 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.

3. 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.

Article 25 – Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

FINAL PROVISIONS

Article 26 – Interrelation and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 – 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.

COMPOSITION OF THE INTERNATIONAL BIOETHICS COMMITTEE (IBC) (2010-2011)

NAME	TERM OF OFFICE
<p><u>BAGHERI Prof. (Mr) Alireza</u> (Islamic Republic of Iran)</p> <p>Assistant Professor of Medical Ethics, School of Medicine, Teheran University Deputy Director (Education) of the Center for Study and Research on Medical Ethics and History of Medicine, Teheran University of Medical Sciences Vice-President of the Asian Bioethics Association</p>	2010-2013
<p><u>BARTNIK Prof. (Mrs) Ewa</u> (Poland)</p> <p>Professor of Molecular Biology and Human Genetics, University of Warsaw Former Vice-Chairperson, Intergovernmental Bioethics Committee of UNESCO (IGBC)</p>	2010-2013
<p><u>BOIRO Prof. (Mr) Ibrahima</u> (Republic of Guinea)</p> <p>Professor of Biology Director of the Research and Studies Centre on Environment, Conakry University Vice-Rector for Scientific Research, Conakry University Chairperson of the National Bioethics Committee</p>	2010-2013
<p><u>BOUSTANY Prof. (Mr) Fouad</u> (Lebanon)</p> <p>Professor at the Medical School of Beirut Secretary-General, Lebanese Ethics Advisory Committee for Health and Life Sciences Member of the National Council for Scientific Research Former President of the Lebanese Order of Physicians</p>	2008-2011
<p><u>BROWN (Ms) Cheryl</u> (Jamaica)</p> <p>Attorney-at-Law Manager of the Office of Sponsored Research, Mona Campus, University of the West Indies Member of the National Bioethics Committee Former Vice-Chairperson, Intergovernmental Bioethics Committee of UNESCO (IGBC)</p>	2010-2013

- CHANDRA Prof. (Mr) Sharat H.** (India) 2008-2011
Emeritus Professor, Department of Microbiology and Cell Biology, Indian Institute of Science, Bangalore
Honorary Professor, Jawaharlal Nehru Centre for Advanced Scientific Research, Bangalore
Director of the Centre for Human Genetics, Bangalore
Member of the National Bioethics Committee
- DAAR Prof. (Mr) Abdallah** (Oman) 2008-2011
Professor of Public Health Sciences and Professor of Surgery, University of Toronto, Canada
Co-Director, Programme in Life Sciences, Ethics and Policy, McLaughlin-Rotman Centre for Global Health, University Health Network and University of Toronto
Senior Scientist and Director of Ethics and Policy, McLaughlin Centre for Molecular Medicine, University of Toronto
Fellow of the Third World Academy of Science (TWAS)
UNESCO Avicenna Prize for Ethics in science, 2005
- DRUML Dr (Mrs) Christiane** (Austria) 2008-2011
Doctor of Law
Managing Director of the Ethics Committee, Medical University of Vienna and the Vienna General Hospital
Chair of the Commission for Bioethics, Federal Austrian Chancellery
- D'EMPAIRE Prof. (Mr) Gabriel** (Venezuela) 2004-2011
Professor of Bioethics, Central University of Venezuela
Director of Coronary and Intensive Care Unit, Clínicas Caracas Hospital
President of the Bioethics Clinical Association of Venezuela
Guest Member of the National Academy of Medicine of Venezuela
- EVANS Prof. (Mr) Donald** (New Zealand) 2004-2011
Professor of Philosophy
Director of the Bioethics Centre, University of Otago
Former member of the National Ethics Advisory Committee of New Zealand
- GARRAFA Prof. (Mr) Volnei** (Brazil) 2010-2013
Director, UNESCO Chair in Bioethics, University of Brasilia
Professor at the Post-Graduate Program in Bioethics of the University of Brasilia
Chairperson of the UNESCO-REDBIOETICA
Editor-in-Chief, Brazilian Journal of Bioethics

- GRACIA Prof. (Mr) Diego** (Spain) 2008-2011
 Professor of History of Medicine and Bioethics, Medical Faculty, Complutense University of Madrid
 Director, Institute of Bioethics of the Foundation for the Health Sciences, Madrid
 Honorary Professor at the University of Chile, University of Lima, Peru, and University of Cordoba, Argentina
 Member of the Royal National Academy of Medicine of Spain
- HU Prof. (Mr) Ching-li** (China) 2006-2009
 Emeritus Professor of Medicine and Senior Advisor, Shanghai Jiaotong University School of Medicine
 Deputy Director, Biomedical Ethics Research Centre, Shanghai Jiaotong University School of Medicine
 Former Deputy Director-General (1988-1997) and former Assistant Director-General (1995-1997) of the World Health Organization (WHO)
- HURIET Prof. (MR) Claude** (France) 2004-2011
 Emeritus Professor of Medicine, Faculty of Medicine, Nancy
 President of the Institut Curie
 Honorary Senator
 Former Member of the National Consultative Ethics Committee for Health and Life Science
- KASHMEERY Prof. (Mr) Amin** (Saudi Arabia) 2010-2013
 Emeritus Professor of Physiology
 Founding Head of the Bioethics Department, King Abdullaziz University for Health Sciences (Riyadh)
 Editor-in-Chief, Oxford Research Forum Journal, United Kingdom
- KUBAR Prof. (Mrs) Olga** (Russian Federation) 2008-2011
 Head of the Clinical Department, Saint-Petersburg Pasteur Institute
 Former Chair, Forum for Ethics Committees in the Commonwealth of Independent States
- LA ROSA RODRIGUEZ Dr (Mr) Emilio** (Peru) 2006-2013
 Surgeon
 Doctor in Anthropology and Human Ecology
 Member of the Peruvian Society of Bioethics
 Former Director of the Health and Society Study and Research Centre (CRESS), France
 Former Vice-Chairperson of the Intergovernmental Bioethics Committee of UNESCO (IGBC)
- LOLAS STEPKE Prof. (Mr) Fernando** (Chile) 2008-2011
 Psychiatrist
 Professor at the Faculty of Medicine and Director of the Interdisciplinary Centre on Bioethical Studies, University of Chile
 Director of the Bioethics Programme, Pan American Health Organization (PAHO)
 Member of the Royal Spanish Academy
 Former Director of the Psychiatric Clinic and Former Vice-Rector of the University of Chile

MAIMETS Prof. (Mr) Toivo (Estonia) 2004-2011

Professor at the Institute of Molecular and Cell Biology, University of Tartu
Director of the National Centre of Excellence for Gene and Environmental Technologies
Former Minister of Education and Research
Former Vice-Rector of the University of Tartu

MARTIN Dr (Mr) Jean (Switzerland) 2006-2013

Physician
Member of the National Commission of Ethics for Human Medicine
Former Chief Medical Officer for the Canton of Vaud
Former Consultant of the World Health Organization (WHO) and the United Nations Population Funds (UNFPA)

MASSOUGBODJI Prof. (M.) Achille (Benin) 2008-2011

Senior Physician, Laboratory of Microbiology, National Hospital and University Centre of Cotonou (CNHU)
Founding member of the Ethics Committee, Faculty of Health Sciences, Cotonou
Founding member of the Pan African Bioethics Initiative (PABIN)
President of the Beninese Association of Fight against AIDS

MATSIEGUI Prof. (Mr) Pierre-Blaise (Gabon) 2010-2013

Clinician and Research Associate, Medical Research Unit, Schweitzer Hospital, Lambaréné
Director of the Research Medical Centre of Ngounié, Fougamou
Chairperson of the National Research Ethics Committee

MC LEAN Prof. (Mrs) Sheila (United Kingdom) 2006-2013

International Bar Association Professor of Law and Ethics of Medicine
Director of the Institute of Law and Ethics in Medicine, University of Glasgow
Member of the Wellcome Trust Biomedical Ethics Panel

MORISAKI Prof. (Mr) Takayuki (Japan) 2004-2011

Professor of Molecular Pathophysiology, Osaka University
Director of the Department of Bioscience, National Cardiovascular Centre Research Institute
Member of the Bioethics and Biosafety Commission, Council of Science and Technology of Japan

ÖZGÜC Prof. (Mrs) Meral (Turkey) 2004-2011

Professor and Director of the Department of Medical Biology, Hacettepe University
Director, Scientific and Technical Research Council of Turkey (TUBITAK) DNA/Cell Bank
Chairperson of the Bioethics Committee of the Turkish National Commission for UNESCO
Member of the European Society for Human Genetics

PERALTA-CORNEILLE Prof. (Mr) Andrés (Dominican Republic) 2006-2013

Medical Doctor

Professor of Bioethics, Santiago Technological University

Member of the Executive Board of the UNESCO-REDBIOETICA for Latin America and the Caribbean

Member of the International Bioethics Association

Founding member and former Chairperson of the National Bioethics Committee

SALEH Prof. (M.) Fawaz (Syrian Arab Republic) 2004-2011

Professor of Law, University of Damascus

Professor and Secretary-General of the Higher Institute of Business Administration

Head of Legal Affairs, University of Damascus

Member and Secretary-General of the Syrian Bioethics Committee

SASTROWIJOTO Prof. (Mr) Soenarto (Indonesia) 2008-2011

Doctor of Medicine

Emeritus Professor, Department of Ear-nose-Throat and Head & Neck Surgery, School of Medicine, Gadjah Mada University, Yogyakarta

Director of the Center for Bioethics and Medical Humanities School of Medicine Gadjah Mada University, Yogyakarta

Member of National Bioethics Committee

Member of National Committee on Research Ethics in Health Sciences

Former Vice-Chairperson of the Intergovernmental Bioethics Committee of UNESCO (IGBC)

SEMPlici Prof. (Mr) Stefano (Italy) 2008-2011

Professor of Social Ethics, Faculty of Philosophy, University of Rome Tor Vergata

Editor of the international journal Archives of Philosophy

Scientific Director, Lamaro Pozzani College, Rome

Member of the Scientific Board, Institute for General and Applied Ethics, Borromeo College, Pavia

SNEAD Prof. (Mr) Carter IV (United States of America) 2008-2011

Associate Professor, Notre Dame Law School, Indiana

US Permanent Observer on the Council of Europe Steering Committee on Bioethics

Former General Counsel of the President's Council on Bioethics

STIENNON Prof. (Mrs) Jeanine-Anne (Belgium) 2006-2013

Emeritus Professor at the Faculty of Medicine, University of Mons-Hainaut

Vice-President and former President of the National Bioethics Committee

Honorary Dean of the Faculty of Medicine, University of Mons-Hainaut

Member of the Belgian Royal Academy of Medicine

TOURE Dr (Mrs) Aïssatou (Senegal) 2006-2013
Immunologist and Researcher, Pasteur Institute, Dakar
Member of the National Health Research Council

TRONTELJ Prof. (Mr) Jože (Slovenia) 2010-2013
Professor of Neurology
President of the Slovenian Academy of Sciences and Arts
Chairperson of the National Medical Ethics Committee
Member of the Steering Committee on Bioethics of the Council of Europe

VUORIO Prof. (Mr) Eero (Finland) 2010-2013
Professor of Molecular Biology
Director of the Biocenter Finland, University of Helsinki
Chair of the National Board of Research Ethics
Former Vice-Rector of the University of Turku

WASUNNA Dr (Mrs) Monique K. Ajilong (Kenya) 2008-2011
Consultant Physician and Specialist in Tropical Medicine and Infectious Disease
Acting Director of the Kenya Medical Research Institute (KEMRI)
Chief Research Officer in Tropical Medicine and Infectious Disease (KEMRI)
Scientific Advisory Committee member for the World Health Organization on Accessible Quality-Assured Diagnostics
Member of the University of Nairobi and Kenyatta Hospital Scientific and Ethics Committee
Board member of the University of Nairobi, Institute of Tropical Medicine and Infectious Diseases

WOOPEN Prof. (Mrs) Christiane (Germany) 2010-2013
Professor of Ethics and Theory of Medicine, University of Cologne
Vice-Chairperson of the German National Ethics Council



United Nations
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CONTACT

Secretariat of the International Bioethics Committee
Division of Ethics and Global Change, Bioethics Programme
Social and Human Sciences Sector
UNESCO
1, rue Miollis – 75732 Paris Cedex 15 – France
E-mail: ibc@unesco.org
Website: www.unesco.org/shs/bioethics

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