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United Nations
Educational, Scientific and
Cultural Organization

International Bioethics Committee of UNESCO (IBC)

THIRTEEN SESSION

PROCEEDINGS

November 2006

PROCEEDINGS

INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)

Thirteenth Session

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United Nations Educational, Scientific and Cultural Organization
Division of Ethics of Science and Technology, Bioethics Section
Social and Human Sciences Sector
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INTRODUCTION

The thirteenth session of the International Bioethics Committee (IBC) was held at UNESCO Headquarters in Paris from 20 to 22 November 2006, bringing together more than 200 participants from some 40 countries.

This thirteenth session was devoted to further consideration of two principles set forth in the Universal Declaration on Bioethics and Human Rightsn adopted by acclamation by the General Conference of UNESCO at its 33rd session, on 19 October 2005: consent (Articles 6 and 7) and social responsibility and health (Article 14). IBC thus examined the work of the two working groups on these subjects, which had met in Paris in June 2006.

These Proceedings comprise, in a first part, the report of the session, the preliminary draft reports drafted by the IBC working groups, the speeches delivered at the opening and closure of the session, as well as the composition of IBC for 2006-2007 and the list of participants in the session.

In a second part, they comprise, in their original language, the presentations of experts invited within the framework of the working sessions on 'Social reposinsibility and health'.

PART I

Chapter 1

REPORT OF THE THIRTEENTH SESSION OF THE INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)

(Ref. SHS/EST/CIB-13/06/CONF.505/5)

by Claude Huriet,
Rapporteur

I. Introduction

1. The thirteenth session of the International Bioethics Committee (IBC) was held at UNESCO Headquarters in Paris from 20 to 22 November 2006, bringing together more than 200 participants from some 40 countries.

2. In accordance with its agenda (see Annex) and the programme of work approved by IBC at its twelfth session (Japan, 2005), this thirteenth session was devoted to further consideration of two principles set forth in the Universal Declaration on Bioethics and Human Rights (2005): consent (Articles 6 and 7) and social responsibility and health (Article 14). IBC thus examined the work of the two working groups on these subjects, which had met in Paris in June 2006.

3. One meeting was also devoted to the presentation of activities carried out and/or planned by UNESCO in the framework of the promotion and dissemination of the Declaration. The Secretary-General of IBC, Mr Henk ten Have, Director of the Division of Ethics of Science and Technology of UNESCO, presented the main features of the Organization's action in that area, in particular the publication and dissemination of the Declaration in the six official languages of UNESCO and in a certain number of national and local languages, the publication of several books concerning the Declaration, the building of national capacities through the establishment of national bioethics committees and the development of the GEObs database and the bioethics teaching programme.

II. Opening of the thirteenth session of IBC[1]

4. Mr Koïchiro Matsuura, Director-General of UNESCO, presided over the opening of the thirteenth session of IBC. In his address, Mr Matsuura welcomed the 17 newly appointed Committee members and then congratulated the Bureau members elected at the twelfth session. He highlighted the fact that the Universal Declaration on Bioethics and Human Rights, barely one year after its adoption, had become a reference text that should now be supported by pedagogical and future-oriented work to develop its principles further, and should be followed up by information and promotion, awareness-raising and knowledge-sharing, as well as implementation activities. The principles chosen by IBC and dealt with during the session were complex and required practical scientific and medical expertise, combined with a social and global vision of the issues addressed.

5. In her address, Mrs Nouzha Guessous-Idrissi, Chairperson of IBC, paid tribute to the former members of the Committee, welcomed its new members in her turn, and presented the activities conducted by IBC since its last session. She also reiterated the willingness and availability of the Committee and its members to assist UNESCO in its activities to promote and disseminate the principles of the Declaration internationally, regionally and nationally. She drew attention to the fact that IBC had decided to set up a working group to continue and further the debate with a view to ensuring that the principle of consent, universally proclaimed, be contextualized in practice and applied with due regard to human dignity, human rights and fundamental freedoms. Lastly, she stressed the complexity of the debate on social responsibility and health, which had begun at the twelfth session and which would be continued at the thirteenth session to give the Committee an opportunity to pursue its work openly and transparently.

III. Social responsibility and health: preliminary report of the IBC Working Group

6. Mr (Prof.) Gabriel d'Empaire, Professor of Bioethics at the Central University of Venezuela, Director of the Coronary and Intensive Care Unit, Clínicas Caracas Hospital, and Vice-Chairperson of IBC, chaired the meetings on the theme of social responsibility and health. These meetings

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1. All the addresses delivered during the session are reproduced in these Proceedings.

were divided into two parts: the presentations by two experts[2] – Mr Schabas and Mr La Rosa – and the consideration of the work of the IBC Working Group on this issue.

7. Mr (Prof.) William A. Schabas, Director of the Irish Centre for Human Rights of the National University of Ireland, focused his presentation on the *meaning and content of the right to enjoy the benefits of scientific progress* and its applications, as set forth in Article 15 of the United Nations International Covenant on Economic, Social and Cultural Rights (1966), and the relationship of that right to Article 15 of the Universal Declaration on Bioethics and Human Rights. He noted that the right had not been developed in international law and that the presence of Article 15 in the UNESCO Declaration could generate renewed interest within the international community and give substance to that right. He also drew attention to the underlying tension between the right to enjoy the benefits of scientific progress as a human right and the right to the protection of intellectual property, in particular with regard to the protection of traditional know-how and knowledge, and the need to strike a balance between these rights.

8. Mr (Dr) Emilio La Rosa, former Director of the *Centre de recherche et d'études santé et société* (CRESS) (France) and member of IBC, began by defining social responsibility as 'the commitment of societies to the field of individual and community health, cognizant of the fact that health and particularly disease have no boundaries and extend beyond the strict limits of geographical borders'. He went on to demonstrate how the principle of social responsibility could be broken down into composite indices, which could be used to monitor global health trends in the light of the principles of the Declaration. The indices proposed – social responsibility and health, maternal and infant mortality, vaccination, maternal and infant care, nutrition, access to drinking water and water purification, and public health and education expenditure – were developed on the basis of internationally accepted indicators used by United Nations agencies (World Health Organization – WHO, United Nations Development Programme – UNDP).

9. Mr (Prof.) Adolfo Martínez Palomo, Coordinator of the Council of Science and Technology of the Office of the President of Mexico, Chairperson of the IBC Working Group on Social Responsibility and Health, presented the work of the Group, pointing out that since this was a new

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2. The statements in their original languages are contained in these Proceedings.

theme in the field of bioethics, the debate that would be held during the session should enable the Group to examine the issue in greater depth and focus its work effectively on the mandate of IBC. He began by remarking that global health conditions increasingly revealed growing inequalities linked to poverty and lack of access to health-care services, both in developing and developed countries; but he also mentioned a number of initiatives taken by international organizations as well as by pharmaceutical firms, that were in accordance with the principle of responsibility set forth in the Declaration.

10. Mr Martínez then presented the draft report structure agreed on by the Group: the first part would be devoted to the contribution of bioethics to the issue of social responsibility and health and would present the context and objectives of the report; the second part would describe the current global health situation; the third part would concern the very notion of health and would specify its determinants and the various interpretations that exist according to cultural context; the fourth part would present the international standard-setting context; in the fifth part, the study of ethical issues illustrated by concrete examples would provide insights into the various responsibilities involved and possibilities for action. Lastly, the conclusions would underline the importance of education.

Discussion

11. Generally, the meeting participants recognized the difficulty and complexity of the Committee's task and the need to define the objectives of the report clearly: the IBC document would aim at redirecting the focus of the bioethics debate, avoiding the pitfall of wanting to tackle all the issues mentioned in Article 14 of the Declaration, together with their social, political and economic implications. Under no circumstances should the Committee repeat and/or duplicate the work or discussions under way in other international organizations such as WHO, regarding health issues, or the Food and Agriculture Organization (FAO), on food-related issues; in contrast, the potential contribution of these organizations should be considered essential and the work already done should be viewed as an invaluable resource for the work of the Committee.

12. It was recalled that the document produced by IBC should address the issue from a bioethical standpoint and that the aim of the discussions was to consider how the debate on bioethics could open up new perspectives, in particular on the way in which each stakeholder should uphold its responsibilities in the context of health promotion. In that regard, it was

noted that at the national level the majority of ethics committees throughout the world focused on cutting-edge practices and technologies, admittedly important but restricted in scope – such as stem cells or pre-implantation diagnosis – rather than on issues such as those addressed under Article 14 of the Declaration.

13. Some contributors referred to the link and complementarity of the principle of responsibility with other principles of the Declaration, primarily *that of solidarity and cooperation set out in Article 13 and developed in* Article 27 in relation to the responsibility of States, but also the principles of the protection of future generations, discrimination and non-stigmatization, or even vulnerability and the environment.

14. Several issues were raised, including the problem of access to drugs, in countries in the South and in the North, in terms of quantity, quality and costs; intellectual property issues and the need to strike a fair balance between individual rights and universally recognized collective rights; the issue of the brain drain and the emigration of health professionals; organ trafficking, etc.

15. It was emphasized that even though there was a genuine problem with regard to financial resources and access to scientific progress for some populations, it was also and above all a problem related to the definition of priorities, budget allocation and availability of already existing resources, and that it was necessary to avoid the pitfall of considering access to scientific progress as an answer to disparities in living conditions among the world's populations.

16. With regard to health, while the development indices explained by Mr La Rosa in his presentation were recognized as an interesting attempt to provide quantitative data on social responsibility, their shortcomings were also mentioned, together with the risk of underestimating other issues existing in the various countries, for instance in relation to social justice.

17. Regarding the stakeholders involved in social responsibility, it was noted that States and, therefore, governments have primary responsibility for health policies, but other stakeholders are also involved – the international community as a whole, including international organizations and multinational firms, and at the national level, society as a whole, including health professionals and non-governmental organizations, and lastly, individuals.

18. The promotion of the development of bioethics education activities, in general and for each responsible stakeholder in particular, was highlighted as essential and as a crucial component of the IBC document.

19. Mr d'Empaire thanked the participants and the Chairperson of IBC stressed how important an open and transparent discussion on a complex and new subject was to the Working Group's pursuit of its work on this issue.

IV. Consent: Preliminary report of the IBC Working Group

20. Mrs (Dr) Aïssatou Touré, Immunologist and Researcher at the Pasteur Institute in Dakar (Senegal) and member of IBC, chaired the meeting on the issue of consent and the work of the IBC Working Group on that issue.

21. Mr (Prof.) Eugenijus Gefenas, Director of the Department of Medical History and Ethics at the University of Vilnius (Lithuania), Chairperson of the IBC Working Group on Consent, presented the structure and the main lines of the preliminary draft report prepared by the Group. The draft report began with an introduction outlining the history of the notion of consent and the relevant articles of the Declaration. The report then considered the general framework of the issue of consent, its link with the principle of autonomy and individual responsibility, the content of the information, the conditions for obtaining consent, the various modalities of consent and other issues. The third part of the report concerned the specific circumstances of the application of the principle according to different types of practices (including clinical practice, biomedical and epidemiological research, public health and emergency situations), subjects (including the issue of individuals incapable or rendered incapable of giving consent, terminally ill patients and organ donation) and contexts (economic, sociocultural, etc.). Mr Gefenas recalled that the last part, which would be drafted at a later stage and feature an executive summary and general conclusions, would deal with the application and promotion of the principle of consent, placing emphasis on the follow-up of consent, the role of ethics committees, the training of professionals and the involvement of the public.

Discussion

22. Generally, the preliminary report was welcomed, and its quality and international scope appreciated. The participants put forward comments and suggestions regarding both the structure and content of the document.

23. First, emphasis was placed on the necessary distinction between the clinical and research context. That distinction should appear more clearly in the structure of the draft report, which might also elaborate on the difference between standard treatment and experimental procedures in the clinical context, and the case of multi-centre research conducted in various countries, in the research context. Further study of those aspects would also make the document more relevant to doctors and researchers in everyday practice and to patients themselves.

24. The meeting unanimously considered consent as a process of continuing dialogue. It is, therefore, important for the draft report, particularly in the section concerning the general framework, to illustrate more clearly the various aspects of the process – the information required and the subject's understanding of it, the forms of expression of consent, the possibility of withdrawing consent at any time, follow-up, and so forth. In any case, the principles of autonomy and consent should not be viewed as a *burden, nor become one, either for the doctor or the patient: the doctor had* the duty to supply the patient with all the necessary information regarding the risks and benefits of treatment or a research study, taking into account his/her vulnerable position. In addition, the practice of consent must not be used as a mechanism to absolve doctors of their own responsibilities with regard to the administration of treatment.

25. Some participants considered that the report should examine in greater depth the issues of withdrawal of consent and the right not to know, and elaborate on the exceptions provided under Article 27 of the Declaration. With regard to the right not to know, it was recalled that that principle – already enshrined in the other UNESCO Declarations concerning bioethics – referred to the right of the individual to decide whether or not to be informed of the results of a diagnosis or a research study and not to the right to refuse information prior to consent: in that sense, while the report could refer to it, that issue did not concern the principle of consent *stricto sensu*.

26. Others considered that the report should also deal with the issue of consent in the context of genetic research, with regard in particular to the use of genetic material for a purpose different than that for which consent was originally given, issues of confidentiality and respect for private life, and consent for potential commercial uses of research findings. It was nevertheless pointed out in that regard that those issues had already been addressed and regulated by the 2003 International Declaration on Human Genetic Data (Article 16).

27. In the context of the consent of individuals incapable of giving consent, the issue of the legal status of the legitimate representative was raised and some criticism was directed at the use of that terminology in the draft report. Similarly, the terms 'competent' and 'incompetent' used in the French version of the document were problematic from a strictly legal point of view and it was suggested that they be replaced by 'capable' and 'incapable'.

28. Some speakers stressed the importance of examining in greater depth cases in which the individual was not able to give consent because of external constraints and/or a situation of vulnerability, for instance in the case of prisoners, both in relation to research and to diagnosis and treatment. It was also suggested that the issue of organ donation should be addressed in the context of both deceased and living donors.

29. Lastly, the part of the draft report concerning the various socio-economic contexts was commended for its innovative nature and transnational approach. Cultural diversity was mentioned as a way of leading to different applications of the principle of consent from one cultural context to another, hence the value of that part of the report. Nevertheless, some participants recalled that, in accordance with Article 28 of the Declaration, the principle of respect for cultural diversity and pluralism (Article 12) must not be interpreted as providing justification to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.

30. Mrs Touré thanked the speakers for their comments and said that the IBC Working Group would bear them in mind in revising and finalizing the report, which would be approved by IBC in its final form at its fourteenth (ordinary) session in 2007.

V. Conclusions and closure of the thirteenth session of IBC

31. At the end of this thirteenth session of IBC, Mr Henk ten Have, speaking on behalf of the Director-General, recalled the role of IBC as a forum for exchange and multidisciplinary, multicultural and pluralistic dialogue and noted that UNESCO's standard-setting action should be envisaged as a catalyst for new discussions, joint reflection and even activities, both internationally and locally. He concluded by emphasizing that the possibility of holding the fourteenth session of IBC in 2007 in Africa was consistent with UNESCO's desire to promote the regional and national implementation of its bioethics standard-setting instruments.

32. Mrs Guessous thanked the members of IBC and all the observers, whose statements had contributed to the joint reflection and discussion that were essential to the continuation of IBC's work on the issues addressed. While the principle of social responsibility seemed difficult to define in view of its cross-cutting nature and its economic, social, cultural and political repercussions, the diversity of the issues and questions raised in the course of the discussions regarding consent had also demonstrated the difficulty of applying a recognized principle in the field of bioethics.

33. The comments and observations made at the thirteenth session were taken into account by the working groups on, respectively, consent and social responsibility and health, which met immediately after the session, on 23 November 2006, to revise the draft reports with a view to finalizing them for the fourteenth session of IBC in 2007.

ANNEX

SHS/EST/CIB-13/06/CONF.505/1
Paris, 5 August 2006
Original: French

THIRTEENTH SESSION OF THE
INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)
UNESCO, Paris, 20-22 November 2006

Agenda

1. *Opening of the Thirteenth Session of IBC;*
2. Presentation of the new members of IBC(*);
3. Presentation by the Chairperson of IBC of the work of the Committee since its Twelfth Session (Tokyo, Japan, 15-17 December 2005);
4. Presentation of activities carried out and/or planned by UNESCO in the framework of the promotion and dissemination of the Universal Declaration on Bioethics and Human Rights;
5. *Consent: preliminary report of the Working Group of IBC;*
6. Social responsibility and health: preliminary report of the Working Group of IBC;
7. Closure of the Thirteenth Session of IBC.

* Item 2 will be dealt with during meetings reserved for the members of IBC.

Chapter 2

STRUCTURE OF THE DRAFT REPORT ON SOCIAL RESPONSIBILITY AND HEALTH

(Ref. SHS/EST/CIB-13/06/CONF.505/4)

Established by
the IBC Working Group
on Social Responsibility and Health

I. SOCIAL RESPONSIBILITY: WHAT BIOETHICS CAN CONTRIBUTE?

- The context: UNESCO, IBC
- The objectives of the report
- The addressees
- What is social responsibility?
- Contributions of bioethics

II. DESCRIPTION OF PRESENT SITUATION: the facts

- The problem (development versus underdevelopment, transnational character, inequities in health, change in public opinion),
- Global health: state of the art (indicators, nature of the disease)

III. EXPLANATION OF THE CONDITION OF HEALTH: OPPORTUNITIES FOR CHANGE

- Socio-economic determinants of health
- Interpretations of health

IV. NORMATIVE CONTEXT REGARDING SOCIAL RESPONSIBILITY

- International human rights law (Declaration of 1948; International Covenant art. 12)
- Existing declarations (WHO, Ljubljana and other statements...)
- Art 14 of the Universal Declaration on Bioethics and Human Rights: genesis and meaning

V. RESPONSIBILITIES AND ACTIONS

- 4 levels of responsibility
- 5 areas of applications of the article
- Proposals, best practices, guidance (see Table)

VI. CONCLUSION

- *Summary of 5 (?) main substantial actions (based on the Table)*
  - education in social responsibility
  - etc...

DIMENSIONS OF HEALTH	*Level of responsibility*			
	Global / international community	**Governments**	**Society (groups, professionals, NGOs)**	**Individuals**
a) **Access to health and essential medicines**	• Examples, cases • Problems, ethical dimension • Solutions / possible approaches to address the moral issue			
b) **Adequate nutrition and water**	• Examples, cases • Problems, ethical dimension • Solutions / possible approaches to address the moral issue			
c) **Improvement of living conditions and the environment**	• Examples, cases • Problems, ethical dimension • Solutions / possible approaches to address the moral issue			
d) **Elimination of the marginalization**	• Examples, cases • Problems, ethical dimension • Solutions / possible approaches to address the moral issue			
e) **Reduction of poverty and illiteracy**	• Examples, cases • Problems, ethical dimension • Solutions / possible approaches to address the moral issue			

Chapter 3

PRELIMINARY DRAFT REPORT ON CONSENT

Established by
the IBC Working Group on Consent

This preliminary draft report on consent has been elaborated by the Working Group established by IBC, taking into consideration the discussion on this issue at the twelfth session of IBC (Tokyo, Japan, December 2005) and on the basis of the discussions at the first meeting of the Working Group (Paris, 15-16 June 2006)

This draft report is preliminary in nature. It is not to be considered definite but as a step in the work of the Working Group and IBC in its entirety. It will be revised and further developed on the basis of the discussions at the thirteenth session of IBC (Paris, 20-22 November 2006).

I. Introduction *(draft version, to be further developed also including elements on the development of consent in clinical practice before the Nuremberg Code)*

1. As a consequence of the medical abuses carried out during the Second World War, the principle of consent was stated in the Nuremberg Code (1947) – the first international basic ethical text – as the first of the ten rules to be respected in conducting research involving the human subject: "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision".

2. Within the UN system, the principle of the free consent of a person undergoing scientific or medical experimentation was then stated explicitly in article 7 of the International Covenant on Civil and Political Rights (1966).

Where the person concerned is not in a position to consent, this article states that a double condition must be met, namely that consent must be given in the manner prescribed by law, and furthermore that the competent individual or authority must be guided by the best interest of the person concerned. Other instruments stipulate provisions on consent in specific cases, for example the United Nations Convention on the Rights of the Child of 20 November 1989 guarantees "the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child" (Art. 12).

3. At international level, the Declaration of Helsinki of the World Medical Association (WMA) on Ethical Principles for Medical Research Involving Human Subjects (adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000) as well as the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences (CIOMS) (adopted in 1982 and amended in 1993 and 2002) provide detailed provisions on consent required in the field research.

4. It should also be recalled that, at regional level, 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 (1997) devotes one chapter to the issue of consent and structures it around 5 articles: general rule, protection of persons not able to consent, protection of persons who have mental disorder, emergency situations and previously expressed wishes.

5. Finally, UNESCO has contributed to the existing international legal framework with the three Declarations adopted in the field of bioethics.

6. The **Universal Declaration on the Human Genome and Human Rights** – adopted by the General Conference of UNESCO in 1997 and endorsed by the United Nations General Assembly in 1998 – deals with the issue of consent in Article 5[1] within the specific framework of research,

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1. *"(a) Research, treatment or diagnosis affecting an individual's genome shall be undertaken only after rigorous and prior assessment of the potential risks and benefits pertaining thereto and in accordance with any other requirement of national law.*

   (b) In all cases, the prior, free and informed consent of the person concerned shall be obtained. If the latter is not in a position to consent, consent or authorization shall be obtained in the manner prescribed by law, guided by the person's best interest.

treatment or diagnosis affecting an individual's genome. The various paragraphs of article 5 are aimed at protecting the rights of the persons concerned, stressing the need to prevent any practices which might be contrary to human dignity, freedom and human rights. The article as a whole sets forth the basic principles that should govern any intervention on the human genome: the principle of prior, free and informed consent, which has as a corollary the right of an individual to refuse to be informed about his or her own genetic data; and all other principles founded on the autonomy of the individual, which follows from the individual's right to privacy.

7. In the **International Declaration on Human Genetic Data** (2003), a number of provisions deal with the issue of consent related to the specific subject of human genetic data and further develop the provisions of the Universal Declaration on the Human Genome and Human Rights on this issue. Article 8(2) deals with consent to the collection of biological samples

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(c) The right of each individual to decide whether or not to be informed of the results of genetic examination and the resulting consequences should be respected.
(d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.
(e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights."

2. *"a) Prior, free, informed and express consent, without inducement by financial or other personal gain, should be obtained for the collection of human genetic data, human proteomic data or biological samples, whether through invasive or non-invasive procedures, and for their subsequent processing, use and storage, whether carried out by public or private institutions. Limitations on this principle of consent should only be prescribed for compelling reasons by domestic law consistent with the international law of human rights.*
(b) When, in accordance with domestic law, a person is incapable of giving informed consent, authorization should be obtained from the legal representative, in accordance with domestic law. The legal representative should have regard to the best interest of the person concerned.
(c) An adult not able to consent should as far as possible take part in the authorization procedure. The opinion of a minor should be taken into

and human genetic data, Article 9[3] is devoted to the withdrawal of consent and Article 10[4] addresses the issue of the right to decide whether or not to be informed about research results.

8. Adopted by acclamation on 19 October 2005 by the 33rd General Conference of UNESCO, the **Universal Declaration on Bioethics and Human Rights** (hereafter 'Declaration') devotes two articles to the issue of consent: Article 6[5] addresses the principle of consent and Article 7[6] covers the case of persons without the capacity to consent.

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consideration as an increasingly determining factor in proportion to age and degree of maturity.

(d) In diagnosis and health care, genetic screening and testing of minors and adults not able to consent will normally only be ethically acceptable when they have important implications for the health of the person and have regard to his or her best interest."

3. "*(a) When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, consent may be withdrawn by the person concerned unless such data are irretrievably unlinked to an identifiable person. In accordance with the provisions of Article 6(d), withdrawal of consent should entail neither a disadvantage nor a penalty for the person concerned.*
   (b) When a person withdraws consent, the person's genetic data, proteomic data and biological samples should no longer be used unless they are irretrievably unlinked to the person concerned.
   (c) If not irretrievably unlinked, the data and biological samples should be dealt with in accordance with the wishes of the person. If the person's wishes cannot be determined or are not feasible or are unsafe, the data and biological samples should either be irretrievably unlinked or destroyed."

4. "*When human genetic data, human proteomic data or biological samples are collected for medical and scientific research purposes, the information provided at the time of consent should indicate that the person concerned has the right to decide whether or not to be informed of the results. This does not apply to research on data irretrievably unlinked to identifiable persons or to data that do not lead to individual findings concerning the persons who have participated in such a research. Where appropriate, the right not to be informed should be extended to identified relatives who may be affected by the results."*

5. "*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

9. The International Bioethics Committee (IBC) has already dealt with the issue of consent when drawing up its reports on specific subjects[7]. However, at its twelfth session (Tokyo, Japan, 15-17 December 2005), the Committee considered that although consent is a traditional issue of bioethics, further discussion and reflection was needed in the light of advances in science and technology as well as the cultural specificities of each society. The Committee therefore decided to set up a working group to focus on the principles of consent as set forth in the Universal Declaration on Bioethics and Human Rights (2005).

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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."

6. "*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."

7. Human gene therapy (Report of 1994, Ref.: SHS-94/CONF.011/8), genetic screening and testing (Report of 1994, Ref.: SHS-94/CONF.011/7), genetic counselling (Report of 1995, Ref.: CIP/BIO/95/CONF.002/4), ethics and neurosciences (Report of 1995, Ref.: CIP/BIO/95/CONF.002/3), bioethics and human population genetics research (Report of 1995, Ref.: CIP/BIO/95/CONF.002/5), access to experimental treatment and experimentation on human subjects (Report of 1996, Ref.: CIP/BIO.501/96/4), confidentiality and genetic data (Report of 2000, Ref.: BIO-503/99/CIB-6/GT-2/3), use of embryonic stem cells in therapeutic research (Report of 2001, Ref: BIO-7/00/GT-1/2 (Rev. 3)), human genetic data (Report of 2002, Ref.: SHS-503/01/CIB-8/3 (Rev.2)), pre-implantation genetic diagnosis (Report of 2003, Ref.: SHS-EST/02/CIB-9/2 (Rev. 3)).

10. Aware of the difficulties that the practical application of the principle of consent may confront, by the present report, IBC wishes to support and clarify the actions that States, organizations and citizens have undertaken or intend to undertake, so that the consent of a person "for any medical intervention (...) or scientific research" be the expression of his freedom.

II. General framework (the principle)

11. Consent of a person constitutes one of the fundamental principles that practices must comply with in the field of application of the Declaration.

12. Article 6 of the Declaration makes a distinction between preventive, diagnostic and therapeutic medical intervention (par. 1) and scientific research (par. 2). Paragraph 1) requires prior, free and informed consent from the persons concerned. It also states that consent should be express where appropriate. As far as scientific research is concerned, according to paragraph 2), consent of the person involved is always required to be prior, free, express and informed. Paragraph 3) introduces the notion of collective agreement and states that in appropriate cases, additional agreement of the legal representatives of the group or community may be sought. However, 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.

13. The very structure of the text of the Declaration clearly demonstrates the close link between the consent of the person concerned by "any preventive, diagnostic and therapeutic medical intervention" and the affirmation of human rights applying to the individual himself/herself whose free decision, autonomy and dignity must be respected in all circumstances.

14. The logical consequence of autonomy is responsibility (Art. 5 of the Declaration). The power to decide for one's self entails *ipso facto* that one accepts the consequences of one's actions, which as one can imagine, in health matters, can be awesome. But of course the person still needs to be informed of the precise consequences of his/her choice, and this in turn leads one to wonder about the conditions under which consent is 'informed' and obtained.

15. And a principle cannot simply be affirmed without examining the conditions of its implementation and the consequences of its application: such is the aim of this chapter. The following topics will be dealt with:

- autonomy and responsibility,
- the content of the information,

- the conditions of obtaining consent,
- the manner of expressing consent,
- specific difficulties in the application of the principle of consent.

II.1. Autonomy and responsibility

16. Article 5 is entitled 'Autonomy and individual responsibility'. The text is clear: "The autonomy of persons to make decisions, while taking responsibility ... is to be respected".

17. Respect for the autonomy of persons to make decisions, while taking responsibility for those decisions, is closely related to the fundamental Article 1 of the Universal Declaration of Human Rights 1948 which holds that all human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood.

18. How can therefore this affirmation, which is also an extension of Article 3 on 'Human dignity and human rights' of the Declaration be contested? Nevertheless, the scope should not be underestimated. The close connection between autonomy and responsibility supposes that the consent freely given by the person concerned be perfectly comprehensible through the information provided, that his/her faculties of comprehension be intact, that he/she has been able to measure the consequences of the illness and its progress, and that he/she comprehends the advantages and disadvantages of possible alternative treatment – all conditions that are sometimes quite difficult to fill.

19. It is foreseeable that if, despite the treatment implemented – and followed correctly – progress is unfavourable, the patient or his/her entourage risks regretting the choice made at an emotional moment, and deems the information provided to be insufficient or misleading.

II.2. The content of the information

20. Article 6 of the Declaration states that 'informed' consent is to be "based on adequate information". As a general rule, an individual has to receive relevant, structured and individually tailored information that makes it possible for that individual to make a decision on whether or not to accept medical treatment or to participate in a research. But it is still necessary to specify what is understood by that.

21. With regard to the consent of the patient with a view to medical treatment, the following important elements should be taken into account:

- the diagnosis, the prognosis of the pathology of the patient;
- the nature, the process of treatment and the benefits that could be hoped for;
- uncertainties with regard to possible undesirable effects;
- the possibility and risks of an alternative treatment or of the absence of any treatment;
- the innovative nature of the treatment.

22. Considerations should also be given to the doctor himself/herself, his/her experience, his/her physical condition and the possible financial benefit.

23. A distinction should be made between the content of the information to be given to a person concerned by research and not by a clinical practice. It is indeed necessary to make the person aware of the aim of the research, the methodology and the duration, the expected benefit for him/her or for other persons concerned, the risks involved as well as the possibilities of alternative treatment.

24. And finally, in accordance with the Declaration, the person should be informed that consent may be withdrawn at any time and for any reason, both in any preventive, diagnostic and therapeutic medical intervention and in scientific research, without any disadvantage or prejudice.

II.3. Conditions of obtaining consent

25. The person carrying out the clinical practice or the research should obtain informed consent before implementation. The information should be "*adequate, provided in a comprehensible form...*" (Art. 6(2) *of the* Declaration) but the long list of information that needs to be given during the meeting between patient and doctor before obtaining consent shows that there are a number of difficulties and pitfalls in practical application.

26. The doctor-patient relationship cannot be equal to equal. It is quite naturally a relationship of dependence that presumes the confidence of the patient in his/her doctor.

27. For the doctor, informing the patient should be more than an administrative procedure and respect for a legal obligation, but translate the consideration that he/she bears for this person who has placed his/her trust in him/her.

28. The emotional context, when a serious illness is disclosed for example, calls for particular sensitivity and tact in the choice of words, in the way explications are given to the patient and responses to his/her questions provided.

29. The information has to be adapted to each person and to their degree of tolerance at a particular moment. The information to be transmitted to each person, in each situation and in each instance depends on too many objective and subjective factors.

30. Furthermore, setting out the risks involved in the course of treatment or research, is a delicate procedure. In certain countries, in the case of a medical accident, jurisprudence convicts the doctor who has not made mention of the exceptional risks that certain clinical practices entail. But an exhaustive list of the major risks could cause the person concerned to be unduly fearful and it is necessary to involve the patient in the knowledge of his/her disease without producing emotional trauma he may not be able to withstand.

31. Besides, some patients do not want to be informed before giving their consent and put themselves completely in the hands of their doctor. Thus, they assert 'the right not to know'.

32. In obtaining informed consent, the patient or a participant in a proposed research, depending on the case, frequently faces doubts about the understanding of the objectives, risks, benefits and expected results of the proposal from the physician or investigator, or even about the rights owed him/her. Considering the role of mediation as a 'contemporary form of the process of dialogue' and an adequate methodology in the analysis of the information supplied to the patient or the possible participant, that must be free of dogmatism and coercion, the hospital ethics committees and the independent committees for ethical review of research could assume the role of neutral and independent mediators upon request by any of the parties involved in the process of obtaining informed consent.

II.4. The manner of expressing consent *(the issue of explicit and implicit consent needs to be further developed)*

33. If consent should be 'express', i.e. leaving no doubt as to the volition of the person concerned, it may be expressed in writing, orally or even by gesture according to circumstances and cultures.

34. A different appraisal exists according to different regions of the world. In fact, whilst in many countries, written consent is considered as offering maximum guarantee (in this case, difficulties can arise from physical impossibility because of certain pathologies, handicaps or through illiteracy), some societies accord absolute trust to parole i.e. to oral consent, to the extent that to ask for written confirmation of a commitment is an indication of mistrust and uncertainty and offends the person concerned.

II.5. Specific difficulties in the application of the principle of consent

35. Three specific difficulties that will be developed in the following chapter of the report, supported by case studies, should be considered in the subject of consent. They concern persons who do not have the capacity to *consent, research carried out on a group or community and the close* connection between autonomy of the person and responsibility.

36. The Declaration recognizes that certain situations do not enable *consent of persons incapable of expressing their consent validly to be* obtained. These are non-exceptional cases of minors and of adults without the capacity to consent as well as certain emergency situations. Whether it be research or medical practice, the Declaration reverts to "the best interest of the person concerned and in accordance with domestic law", which constitutes in certain countries a 'person of confidence' or a 'legal representative' whose legal status is generally rather vague.

37. It cannot be ignored that such situations illustrate ethical tensions that no normative text can resolve. The example, given so many times because it clearly illustrates the dilemma with which the doctor or researcher is confronted, is that of senility or Alzheimer's disease which prematurely obfuscates the intellectual capacities of the patient afflicted and whose free 'informed' consent is problematic before becoming impossible.

38. Should one refrain from any treatment or research – which would destroy any hope of progress in the understanding and treatment of the illness? It is not for the Declaration to provide a response that should be given by ethics committees – whose creation is strongly recommended (Art. 19).

39. Advance directives have been increasingly considered as a means to express the autonomy of the person concerning decisions with respect to her/his health if he/she becomes unable to give valid consent because of incompetence (confused or unconscious patients). They contain, among

others, instructions concerning medical or non-medical treatments or interventions the person requests or refuses.

40. There are two major types of advance directives: (1) instruction directives related to defined situations and (2) 'proxy' directives with the designation of a 'representative' entitled to take decisions in the name of the incompetent patient (surrogate decision-maker). Both types are preferably associated to cover at best the variety of possible needs or situations encountered.

41. Advance and 'proxy' directives apply to all medical situations, including problems related to the end of life and the numerous cases dealing with persons whose capacity of judgment is deteriorated, making them unable to express competent consent.

42. Advance directives have to be expressed by the competent person after due information and without any constraints from family or environment. They should be valid for a defined period (usually 3-5 years) and can be revoked or modified at will and at any time by the competent person.

43. Legislations and regulations dealing with advance directives and surrogate representative with respect to health and end of life are subject to rapid evolution. In some countries, such directives are not required to follow specific conditions of form; as other wills, they do not need to be established in an official document; further, to the extent that credible witnesses can attest their existence, they shall be taken into account even if they are not in writing. However, in other countries, by law, advance directives and/or designation of a surrogate representative have to be in writing in an official document.

44. Finally, in the area of research carried out on a group, or public health measures such as collective vaccination, lies the question of the primacy of consent of the individual compared to the agreement of the representatives of the group or the community. The Declaration stipulates that in no case, "a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent".

III. Circumstances of application

III.1 Consent in various categories of practices

45. Prior, free and informed consent is a major pillar of health care. For it to be valid, consent should be based on precise, sufficiently complete and candid information to the patient from the care provider (who has a

systematic *duty* to provide it). According to circumstances, modalities of obtaining consent may vary; experience, common sense, practical wisdom and (to an extent to be evaluated) socio-cultural habits play a role here. The basic point is that, apart from exceptions some of which will be mentioned, the patient autonomously decides whether to accept or not any care or other measure/procedure proposed to him/her.

III.1.1. Clinical practice – Between provider and recipient of health care

46. It should be underlined that, in general, adequate information of the patient is the *condition sine qua non* for consent to be validly obtained; without adequate information, there can be no validly-given consent. One should emphasize that it is a **systematic duty** of the provider to give information which is sufficiently complete (including possible adverse effects/reasons for concern), understandable and candid. In this respect, the notion of *therapeutic privilege* which appears in certain deontological codes cannot be supported anymore – in any case as a privilege. There might sometimes be a place for a therapeutic *exception:* leading in exceptional circumstances to limit or delay the transmission to the patient of some information. Nevertheless, the rule is that information is given completely and as soon as it is available.

CASE STUDIES

- Taking of blood
- Emergency situations

47. As clinical practice does not include only situations of major health problems, invasive procedures or negative prognosis, various ways of obtaining consent are acceptable, according to different cases. One may in this regard consider local circumstances and socio-cultural features, while holding fast to the principles of bioethics as set forth in the UNESCO Declaration, and to the rules of medical/health law.

Primary medical care

48. There are a number of routine, simple non invasive, acts in daily medical practice the nature of which can be assumed to be known from the usual patient: e.g. measuring blood pressure. Medical physical examination (palpation or passive movement) of a body part which hurts or is the object of other complaints might also be undertaken without requiring an explicit formal consent. When the doctor says 'I am going to examine your knee – or your abdomen', the fact that the patient shows no opposition can be considered a tacit agreement. Quite different is the situation in which a care provider would perform a gynaecological examination in a patient who came for an ENT

discomfort... Then, precise information on the need for this additional examination should be given and explicit consent obtained (NB: PSM, *professional sexual misconduct*, is a problem which needs much attention and preventive/corrective measures). In such a situation, prior, free and informed consent should be given, though it might not be necessarily a signed one.

49. Further, a lot of primary care, especially in countries with an aging population, is related to chronic diseases, including repeated (routine) consultations/visits by the patient. In such conditions, one would not require that the provider informs each time on practically unchanged features of the patient's condition and treatment.

Care which includes risks, side effects, mutilations

50. The more invasive, mutilating (major surgery) or debilitating (chemotherapy) a treatment, the more explicit and categorical the consent will need to be. Examples: surgery with losses which are practically or symbolically severe (mastectomy, possible loss of sexual potency, anus praeternaturalis, limb amputations), hazardous surgery on the spine – with possible paralytic sequelae, heavy cancer treatment with a serious loss of quality of life for months (it should be compared with the potential quality of life and length of survival without such heavy therapy).

51. The same is true for evident reasons for surgical sterilization or termination of pregnancy; as well as for medical assistance to procreation (in view of the possible length and costs of such treatments, both in psychological and financial terms). In the latter cases, a **signed consent** to treatment would be a requirement; it serves as protection for the practitioner in case a complaint might be lodged later that the procedure was not undertaken with the fully informed consent of the patient about possible consequences.

52. It might be prudent to ask for a signed consent in a number of other situations such as those mentioned in the first paragraph above. It is routinely requested before aesthetic surgery, where the quality of the result might well be appreciated differently by different persons. And where the question might be asked, from a juridical point of view, whether there might not be an obligation of result for the physician – rather than the obligation of means in usual medical practice.

Quality of the relationship

53. In the caring/therapeutic relationship, the characteristics of obtaining consent will depend on:

- the duration of the relationship, and the possible longstanding mutual trust – or absence of established trust,
- the fact that, given the complaint, certain acts are evidently needed (even the little-educated patient will know it),
- the invasive character of the procedure, and of the importance of possible adverse side-effects,
- they will depend also on the economic consequences, especially when the related cost is not or not entirely covered by an insurance mechanism.

54. As in all aspects of health care, common sense, proportionality and practical wisdom (*phronesis*) are qualities expected from the professional. Whatever the case, *the golden rule* remains: if there is any doubt that the patient has fully understood and that he/she has consented to the procedure/treatment, the provider should verify explicitly that it is the case.

Mental illness and consent

55. It has long been accepted and practiced for a long time that a psychiatric condition might be a reason allowing to forego/waive the consent of the patient – who is not in a condition to be a judge of his/her best interest (see section III.2 of this report). It should be underlined however that it does not mean that the patient's expressed opinion should in no way be taken into account anymore, that it can be neglected. The situation should be judged professionally, with nuance and proportionality and, to the largest extent possible, one should consider carefully what the patient manifests. This holds true as well for other persons viewed as incapacitated, lacking capability of judgment (*capacité de discernement).*

How long is informed consent valid?

56. The question may be legitimately asked. It should be looked at and solved according to the concepts described above. The major appreciation to be made is whether, since the moment the original consent was given, there have been significant changes in the health problem, in the therapeutic proposals, in the life and circumstances of the patient and his/her context. Again, the importance/heaviness of the decisions to be made and of the procedures to be undertaken is a major consideration.

57. In the follow-up of a chronic disease in the framework of a longstanding therapeutic relationship, there is usually no point in requesting formally repeated consents, as long as the patient goes along with the

investigations and treatment. Would new methods appear (drugs, surgical possibilities), then it is necessary to update the information given earlier and to ask whether it changes anything in terms of consent.

58. What is said above doesn't mean that one should not present several times relevant information to the patient, and thus make sure that his/her consent is still valid. Be it recalled here that, often, the patient doesn't understand all of what is said, or all correctly, the first time the practitioner provides information. Thus, it is often wise and even necessary to give the same information again, maybe under another form, later.

59. *One more remark: the fact that a given person wishes a certain* treatment, medical or surgical, does not allow the practitioner to carry out procedures which are unnecessary, contra-indicated or detrimental to the patient's health. A patient cannot order a professional to act when the latter considers, in conscience, that it should not be done (that there is no medical indication).

Consent can be withdrawn freely and at any time

60. It follows from the notion of free and informed consent that it can be withdrawn at any time. The patient is autonomous and decides about what appears to him/her to be the best course of action (or non-action). There might be very rare exceptions to that rule: it could be unadvisable to interrupt prematurely a given sequence of treatment; however they are indeed exceptional and need not be discussed in detail here.

61. In the spirit of the Declaration, the correct practice, would a patient withdraw his/her consent, is to expose clearly and serenely the possible consequences of such withdrawal, making sure that they are understood by the patient – who assumes the ulterior responsibility. The same applies in case of *initial* refusal of a proposed measure (investigation or treatment). This refusal is to be respected but there is a duty to insure that sufficiently complete and understandable information has been given.

62. An important rule in relation with **refusal of care** deserves to be recalled: *such refusal should never lead to less diligent care of the patient* (apart from the refused one) or to any kind of discrimination. The same holds true for research (see below): persons refusing to participate should never be put at a disadvantage because of the decision and should continue to benefit from all standard care their condition requires.

III.1.2. Consent in biomedical research

CASE STUDIES

63. Here also, the consent issue and the practical circumstances of obtaining it vary according to several criteria, in particular:

- whether the research is on voluntary healthy (non-diseased) volunteers,
- in research in which diseased people participate, whether they are likely to benefit directly or indirectly from it or not.

64. There are several other aspects to be considered, in relation with the civil status and ability to judge/decide/consent of the participants in research (minors, incapacitated persons, etc). They are treated in a following section of this document.

65. Dealing with ***healthy volunteers***, the significant fact is that those persons have not, in the first place, requested care/involvement in a medical procedure. They accept to be part of research, either for altruistic reasons or because they earn money or another reward doing it. Being in a situation of non-demand, they must be given particular assurance that, would anything adverse happen, they will be well protected/cared for (civil liability of the researcher). The risks involved in the research should be particularly minimal. [Participation should be described in precise terms in writing; signed informed consents are mandatory.]

66. Several countries have established registers of healthy volunteers, enabling to follow the frequency with which they are 'employed' and possible *undesirable consequences. A factor which pushed to such registering is the* recent tendency, within Europe for example, to enlist as health volunteers persons coming to a given country from another one, as tourists for a limited period. This might lead to a certain dependency (because of the profit involved, which might be sizable in terms of the volunteer's country conditions).

67. Generally, diligent care should be taken to assure that healthy volunteers are not under pressure to participate. Thus, one should refrain from requesting prisoners, or others in a dependent situation, to be involved in such research.

68. Regarding research with ***diseased persons for whom there is no foreseen benefit***, the situation is somewhat akin to what was just said for healthy volunteers: the risks should be minimal and provisions should be made to avoid any damage they might suffer from the research (or, as might happen, to alleviate or compensate any such damage).

69. For ***patients who might benefit from the research***, the possible risks linked to the project – which should always be as limited as possible – have to be considered in relation to the severity of the patient's condition and to the chances of a significant improvement. Desperate situations allow riskier procedures than research about pathologies that do not represent a threat to life or to major functions.

70. A key ethical principle of research with human subjects is that studies should not be conducted with incompetent, e.g. intellectually impaired persons that could be undertaken with scientific validity on persons who can provide their own competent, informed and free consent.

71. In principle, one should refrain from using vulnerable persons (see section II.3 of this report) in research, except when the project is likely to bring them direct benefit or when no comparable study can be undertaken – and relevant results obtained – with other patients.

72. The right to stop participating in the research project is also guaranteed, unless such withdrawal may result in undesirable outcome to the participant in that situation agreed among professionals.

III.1.3. Consent in epidemiological research

CASE STUDIES
• HIV

73. The objective of epidemiological research is to elucidate the characteristics, in a population, of the prevalence and incidence of a disease or other health problem (accidents, battering/violence, intoxications...) and of the distribution of the problem (e.g., according to age, sex, type of work, social conditions, place of residence, daily habits/behaviours).

It might include a variety of modes of participation, including:

- use of already collected data (in a medical, sociological or other investigation, possibly coded or anonymized);
- filling out a written or electronic questionnaire;
- answering an interview;
- providing samples of biological matter (blood, urine, saliva etc.);
- performing, in various ways.

74. Understandable and sufficient prior information of the persons is of course a requirement. Regarding consent, the fact of freely filling out a questionnaire or answering an interview is a factual evidence of consent, but participants in the research should be completely informed about the use made of the data they provide, including how and when they might be coded or anonymized, and about their right to quit the project at any time. For biological samples, their potential use and its limits should be clearly defined. In some cases, whether it is possible or not to go/trace back a result to the participant/informer is a major ethical issue.

75. In any event, in research studies that include genetic data from biologic samples, informed consent should comply with the provisions of the UNESCO's Universal Declaration on Human Genome and Human Rights and the International Declaration on Human Genetic Data.

76. The involvement in research of many members of a given community poses specific questions (to which article 6 (3) of the Universal Declaration refers). Such has been the case in recent years, for example in Iceland, a relatively isolated country during centuries with a very homogeneous population and excellent genealogical records. This is of great interest for studies about genetic predispositions to certain diseases. A desired collective agreement should be sought in a societally accepted, democratic, fashion. But it should always remain possible for individuals to refuse to collaborate. It should be avoided to give them any pressure when they would refuse to join such a programme or withdraw from it.

Can data collected for one study be used for other studies?

77. The principle of informed consent demands that the person is informed completely about the use made of the data/material she provides. There are however situations where opportunities to use already collected material for another research appear later only. From a scientific point of view, one wishes not to forego such possibility. The consent issue here is a delicate one. Whenever possible, one may go the participants and ask for their consent for the new line of study. In situations where this is not practicable, countries or professional societies should have established specific regulations, including examination by expert bodies, to waive the individual consent requirement. In addition, individuals should be entitled to have a right to withdraw from the research project or have some kind of way to protect their right. Also, another chance regarding a consent should be given when research progress would create a different situation on the outcome.

78. It is not acceptable to ask participants in a research to give an *overall prior consent* to the effect that they would agree to any study which can be done with the data or samples they provided. Consent should be based on the certain limited purpose of the research project.

79. The above considerations hold true, *mutatis mutandis*, for basic/clinical research (see above).

III.1.4. Consent and public health

80. First, it should be noted that epidemiological research is often of public health importance (as, indeed, clinical research can be). What has been said above applies.

81. The major issue here is the fact that public health measures, aiming at avoiding, eradicating or alleviating a problem of importance for the whole population – or groups within it, might interfere with the free determination of individuals. For example, the threat of an epidemic legitimates the public hand to order compulsory measures; a well-known example is the *quarantine,* enforced since the XIVth century in Italy to try to limit the spread of the plague (Black Death).

82. Today, such threats may lead to ordering the immunization of an entire population or categories within it (e.g. persons employed in the health field). Further, even without immediate epidemic danger, it might be justified to declare immunizations compulsory in order to insure a sufficient coverage in the population.

CASE STUDIES

- Vaccination
- Collection and use of genetic data

83. Around 2005-2006, numerous countries made plans in respect to avian influenza and the major danger it would represent in case of a mutation allowing the disease to pass from human to human. In an epidemic, the right to freely choose one's physician or hospital might well be suspended and patients directed to place of treatment according to an established plan (that also would be an exception to the required informed consent of the individual). In fact, it is clear that health and hospital planning for a country or region, meaning concentrating technical / technological resources in certain points rather that in others, also induces, *per se*, limits to the possible choices by the persons. Such constraints however are usually understood by the public.

84. It should be recalled that WHO is presently working on a new project to study the wide range of challenging ethical issues raised by a potential influenza pandemic, so that to be able to provide Member States with comprehensive, practical guidance on how to incorporate ethical (and related human rights and legal) considerations into their plans and preparation for, and response to, pandemic influenza.

85. Similar issues are raised by other public health measures which are benefiting the population as a whole and sometimes imposed. Till recently, in parts of Switzerland there was a State monopoly on the trade of salt and for decades salt has been iodized in order to prevent hypothyroidism and goiter (with very good results). People who didn't want to ingest iodine with salt had no choice then; today however, it is possible to buy iodine-free salt also. In parts of the United States where the water supply was fluorized, which is beneficial in terms of dental caries prevention, one has seen political struggles over it.

86. In occupational medicine, a part of public health, compulsory periodic controls are prescribed in jobs including serious risks. This is legitimate and prudent; in terms of consent however, the worker might have no choice but accept the controls (if he wishes to keep his job).

87. Though they are not imposed by health authorities or practitioners, one may note here that traffic regulations such as speed limits and obligatory use of seat belts, which have major positive public health consequences (diminution in the number of accidents and their long-term sequelae) represent, *stricto sensu*, limits to the exercise of the individual's free will. From a societal and civic point of view, they should be accepted and even welcomed.

Investigation and/or treatment without consent in specific cases?

88. In order to elucidate concerns of public health importance, for example communicable diseases, health authorities are legitimately allowed to order, even against their will, specific medical investigation of diseased persons or of people around them. They might also order autopsies for the same purpose.

89. The issue of compulsory examination or treatment of an individual to protect the health of others is a debated issue. Would potentially a severe disease be passed in daily life circumstances and unknowingly, e.g. in public transport or space, authoritarian measures might be justified. Regarding sexually transmitted diseases, in which there is little or no danger of a large scale epidemic and where one might consider that persons at risk

(sexual contacts) act freely and usually have adequate information about possible threats to their health, some consider it logical nevertheless to trace contacts and examine/treat them even without their consent, while in other parts it is now viewed as an undue infringement on the individual's autonomy.

90. A situation in which compulsory treatment is permitted in some circumscriptions is drug addiction; the results of such measures however are very disappointing; without their full consent and personal commitment it proves quite difficult to help persons to quit the habit. A related issue is the one of the pregnant woman who goes on using drugs at the end of a pregnancy and thus harms her child. Some States in the United States of America permit courts to order a compulsory caesarean section against the will of the woman; such a decision cannot be made in Western European legal systems, which consider that it is too large an infringement on the autonomy of the mother. Medically, international experience with court-ordered caesarean deliveries is mixed at best according to experts, who recommend caution.

91. There are discussions about the possibility of castrating persons with severe sexual perversions which prove not be controlled by any treatment. It has been suggested as the only procedure which would permit to let such persons go out of prison – or other confinement – without being dangerous again. It is difficult to weigh whether, even with the individual requesting it, it should be allowed. And it is certainly unacceptable if he refuses, as it represents a most important damage to physical integrity.

III.1.5. Emergency situations

92. They pose specific questions because of the need to act rapidly to save the patient's life and/or limit sequelae to the maximum possible extent. This represents evident constraints in terms of obtaining the **prior and fully informed**, serenely given, consent of the person.

93. In addition, the patient might be confused or, worse, in an unconscious condition and thus cannot give a valid determination. One has then to deal with two issues:

- the substitute/proxy determination by a legitimate representative (see section III.2 of this report);
- the general professional/ethical duty of the health practitioner to provide care, save/prolong life, alleviate suffering. This entails particular difficulties when the practitioner considers that the proxy decision is not in the best interest of the patient.

94. According to the principle of patient's autonomy, the golden rule is his/her presumed will in the given situation. What was just said notwithstanding, the personal conviction of the health professional should not override a known valid prior determination of the patient. However, it should be noted that the actual situation might not be appropriate for judging based on the presumed will.

95. It is necessary here to underline the relevance of advance directives (also called *living wills*) issued by the patient, making clear what kind of treatment he/she wishes – or doesn't wish – in particular cases.

96. Until recently physicians often considered that such directives were useful documents that they could refer to, but that they were under no duty to follow them; today the position is more and more that, indeed, advance directives are binding for the care providers, who could act against them only for stringent, imperative, reasons. Such position is couched in health law in several circumscriptions. This holds true for precise directives expressed by a competent person – and assuming that there haven't been major changes in his medical or personal situation since the moment the directives were established – caution and whenever possible verification is in order regarding directives which would be ten or twenty years old.

97. Supposing there are no relevant advance directives, the care providers will gather the opinion of the person's relatives and/or close friends about his/her presumed will – while remaining aware of possible conflicts of interest between them and the patient. If in doubt, the decision would go toward measures most likely to save the patient, respectively limit the adverse consequences. In case of opposition between the professional and the family/friends, and assuming that some delay is tolerable, one may seize the civil judiciary authority/court responsible for protecting/preserving the rights of incapacitated persons (*autorité tutélaire* in French), requesting it to decide. NB: the same holds true when a professional has serious misgivings about decisions made by parents or legal representatives about the treatment of young children.

98. In any case, as soon as he/she is again in a position to decide, the patient should be fully informed of the situation and of the medical measures undertaken while he could nott be aware of them, and his/her consent should be obtained before going further with the treatment.

99. *Research* projects in emergency situations pose comparable questions. They should be looked at in considering what has just been said as well as what appears above about clinical research.

III.2 Consent in various categories of subjects

100. Article 7 of the Declaration stipulates that special protection is to be given to persons who do not have the capacity to consent to research or medical practice. A person not able to consent may be a minor, a mentally disabled or legally incapacitated adult, either for a given period or permanently. The protection shall be given by domestic law and the best interest of the person as well as his/her participation in the decision-making process should be sought. In the case of research, the Declaration establishes the general principle that such research may only be carried out if it is of direct benefit to the health of the person concerned, 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. Exceptionally, it stipulates that research that is not expected to be of direct benefit to the health of the person concerned may only be carried out with the utmost restraint, taking care to expose the person to minimal risk and minimal burden and in the interests of persons in the same category.

101. Autonomy is often defined as self rule and refers to the right of persons to make authentic choices about what they shall do, what shall be done to them and, as far as is possible, what should happen to them. However there are numerous sets of circumstances where the capacity to exercise autonomy is subject to limits without calling respect for autonomy into question. These are examined in the following sections.

102. Limits to the capacity to exercise one's autonomy need to be carefully defined. Their causes might be either external or internal to the decision maker. For example, with respect to external limits the capacity can only be constrained in rare sets of circumstances each of which involves the protection of the autonomy of others. In some cases authorised personnel can arrest, question and imprison others for breaches of the law within carefully determined and proper limits. In other cases medical personnel can compulsorily detain mentally ill persons for protection and treatment if they constitute a danger to the freedoms and safety of others. Similarly those who suffer from very serious infectious diseases may be compulsorily removed from their place of abode or work in order to protect the health of others. Such justified restrictions of the liberty of people to choose for themselves are very few and are highly constrained in order to maximise respect for autonomy.

103. These restrictions can be regarded as an impairment of the capacity of people to make authentic choices about their own behaviour and activities. Such a description is open to misunderstanding as, in general, impaired

capacity is referred to as **incompetence**, which is standardly identified in people who, for reasons internal to themselves, do not have the capacity to make authentic choices. These latter groups of persons lack the ability to make authentic choices irrespective of their external circumstances, such as being in contact with others whose welfare is threatened by their condition. In this sense incompetence can be defined as lacking the freedom to make authentic decisions because of an inability to make such decisions even when given the opportunity. Various groups of people have been traditionally labelled in this way. They include people with learning difficulties, the mentally ill, children, confused elderly and unconscious people.

III.2.1. External constraints on the capacity to choose

104. As noted above, one's ability to make decisions might be properly constrained by external circumstances to protect the interests of others, but such situations must be narrowly construed in order to preserve respect for autonomy. This is illustrated by the following example. Outwith the constraints imposed by the courts and police doctors alone are given such powers in order to protect the health of others. There have been efforts made by some to extend these powers, thus making medicine a form of social control to achieve political goals rather than health goals. The psychiatric diagnosis of sluggish schizophrenia was employed by Soviet psychiatrists to impose social control over political dissidents. The diagnosis was used to identify people with non-psychotic symptoms of schizophrenia, people who, it turned out, were deviant in their perceptions of the reality which was the imposed ideology of the day. They were forcibly removed to psychiatric institutions and subjected to compulsory treatments of radical kinds. The groups of psychiatrists involved were excluded from the World Psychiatric Association until such improper use of clinical interventions were removed. Where the law allows medicine to restrict the capacity of people in this way the power is qualified by providing protections to those affected in the form of reviews and safeguards of various kinds.

III.2.2. Internal restraints on the capacity to choose – incompetence

Criteria of incompetence

105. The criteria used to identify the groups of people described as incompetent have included the ability to understand the issues involved in the decisions at stake, the ability to evaluate these rationally, a reasonable outcome of the decision and evidence of a decision being made.

106. While these look like objective criteria there are difficulties in their application. Inevitably the assessment of any judge of the competence of others is made from that judge's perspective of what it is to understand, what is rational and what a reasonable outcome would look like. But there might be disagreement about each of these.

i) For example the second criterion cannot discriminate definitively between patients who might be risk takers in life and clinicians who are cautious. What appears to be rational to the former might not appear rational to the latter.

ii) People might also disagree about what constitutes a reasonable outcome to a decision. Here there is a danger of informed consent procedures, set up to ensure respect for autonomous decision-making, being rendered meaningless if the patient does not choose the outcome preferred by the clinician. For example, a patient might not wish to receive possible life-saving treatment for a malignant disease but rather maximize the quality of their remaining days by avoiding the rigours of cytotoxic medication. To interpret such an outcome as unreasonable would compromise the consent process for if the patient chooses the treatment he/she will be regarded as competent and so undergo the procedure and if he refuses then the procedure will still be carried out as the unreasonable choice will indicate his/her incompetence and thus invalidate his/her refusal.

iii) Assessing the degree of understanding of data offered to a patient is not an exact science either. Some people demand a more detailed grasp of a wider range of facts than others in accepting that a decision maker understands a situation. To set the standard too high threatens to undermine the freedoms of inexpert patients when judged by their medically expert clinicians.

iv) The general safeguard of the freedom of patients in these situations is that no judgment of competence should be called for unless there is evidence to undermine the normal assumption that people are normally competent to decide for themselves. In other words, proof of incompetence is required not proof of competence. Foolish decisions can be voluntarily made by the most competent people and the freedom to so act should not be restricted by imposing over-strenuous standards of competence.

III.2.3. Classes of incompetent patients

Neonates

107. Neonates cannot think like adults – indeed they cannot think at all. It is therefore impossible for them to be able to make decisions, to understand information, to process information rationally or to desire reasonable outcomes. In other words they can satisfy none of the standard criteria of competence. Yet decisions have to be made about them. The best candidates for this role are the parents, on the assumption that above all people they will have the best interests of their child at heart.

108. Sadly, in some cases parents do not make decisions in the best interests of their children. This is problematic in health care settings, especially when the results of the decisions could be very damaging to the health of the child. In most societies provision is made to protect children whose parents are not capable of, or willing to provide the necessaries of life for their offspring. In those cases it is possible for the state to step in and remove the decision-making role from them. This is done by making the child a ward of the court and placing that role in responsible hands. This step should be one of last resort as it usually has serious negative repercussions in the relationship between the health professional and the parents. Such an outcome bodes ill for the future welfare of the child who is less likely in future to be presented for health care surveillance and care at appropriate times.

Children

109. It might appear that all children, similarly, by their very nature, are incompetent because they cannot think like adults. Whilst this is certainly true of very young children, as children develop they show marked differences from each other. Fixing a chronological age such as 16 years to mark the attainment of competence is unsafe. The United Nations Convention on the Rights of the Child asserts that children have the right to say what they think should happen when adults make decisions that affect them and to have their opinions taken into account (Art. 12), have the right to get and share information (Art. 13), have the right to think and believe what they want and practice their religion as long as they do not stop other people enjoying their rights (Art. 14), and have the right to privacy (Art. 16). All these assume growing levels of competence which have to be taken seriously.

110. But when will they be capable of making their own decisions? The idea that they will attain a magical common age when this occurs was tested in the courts in the United Kingdom in the Gillick case (Gillick vs West Norfolk and Wisbech Health Authority & DHSS). In that case Mrs Gillick, a mother of teenage daughters, objected to the proposal to make contraceptive advice available to young women without the knowledge of their parents. She challenged the proposal in court and won. However the matter went to appeal and the decision of the lower court was overturned. In the celebrated judgment made by the Appeal Court the point about the different rates of maturity attained by young people at given ages was considered. The recommendation was that an arbitrary chronological age should be replaced by a test of maturity of the child to understand the nature of the decision to be made and the consequences likely to follow from the selection of the available options. Such a standard has been widely adopted in other countries since the judgment was made. Of course this places an additional burden on the health professional involved in seeking to offer a clinical intervention or advice. However this is seen as essential in order to safeguard the rights of the child mentioned above.

111. Clearly some decisions are easier to make than others insofar as they are more readily understood and the consequences of a poor choice are less onerous or dangerous. One might properly apply some higher test of competence for decisions of greater moment. But here it is important to be cautious. This could be a ploy adopted to undermine the rights of mature children to make their own decisions by setting the standards of maturity unacceptably high. Adults too are often competent to make some kinds of decisions but not others and we might devise more stringent tests for the weighty decisions in their case. But the standards should be no higher in the case of children than it is in the case of such adults if we are to have proper regard for their autonomy.

Child research participants

112. Research activities involving children are carried out to learn more about the nature of paediatric development, disease and potential treatments. Though one might hope that it will in some cases be beneficial to the research participant the activity cannot be said to be specifically designed for this purpose because of the nature of the research question. Here it differs from clinical treatment *per se*. As a result, parents cannot consent their children into research on the basis of the assumption that they are the ones who have the best interests of their child at heart, for the

research procedures are not aimed specifically to ensure the best interests of their child. We do not know at this stage whether they are likely to be beneficial or not – indeed that is the research question being asked. Those who stand to benefit are future children for whom the results of the research will be valuable in informing their treatment.

113. But it is not acceptable to abandon this group, or indeed other specific groups of people who lack the ability to make their own choices to the suffering and consequences of diseases and conditions peculiar to them. Research into paediatric illness and child development, schizophrenia, degenerative neurological disease and so on is desperately needed. There are no alternatives but to use members of these groups to conduct such enquiries. So what is to be done?

114. One crucial safeguard required, to minimise loss of respect for autonomy in this connection, is the general rule which is applied to all groups of patients deemed to be incompetent, viz. where the research into their various conditions can be carried out by employing competent participants then incompetent participants should not be used.

115. But what of the many situations where there is no alternative but to use participants who are not capable of deciding for themselves whether to be involved in research? The answer will vary from group to group but here we are specifically concerned with the case of children.

116. The approach is best illustrated by using a parallel example, viz. where the question arose about the propriety of carrying out a clinical procedure on a healthy infant for the benefit of its sibling. John was a small baby diagnosed as suffering from myeloid leukaemia. He was in a parlous state of health and the only possibility of rescue lay in a bone marrow transplant. But where could a matching donor be found in time?

117. He was not an identical twin but his next best chance was to identify siblings who would be likely to provide the best candidate tissue. He had six siblings whose ages ranged from seventeen years to two and a half years. The first five were tested and though some of them would have provided good matches for others of them none of them provided a good match for John. Finally his youngest brother was tested and found to be as near an ideal match as could be hoped for. The parents were desperate to see their baby's life saved and would give immediate consent. But they had a conflict of interest. Whilst it was evidently in the interests of the recipient child for them to consent to the procedure it could not be said to be in the interest of the donor child. The clinicians therefore did not simply accede to their

wishes but reflected on the case together with a class of medical students. It was concluded that despite the facts of the inexplicable, unpleasant and painful few days which the donor would experience in donating tissue the time would come when a mature view of it would be formed. The overwhelming chances were that he would be grateful to hear when old enough that he had been the means of saving his brother's life – or at least that he had been the means of giving a brother he was never to know the best possible chance of life.

118. The consent was therefore called a *hypothetical consent*, that is, a consent which would likely be in accord with the feelings of the donor when mature. Such an outcome would, of course, be less likely if undue risks were taken with the donor's life such as the explantation of a whole organ.

119. Given a carefully minimised level of risk, the child might also be grateful to learn that the use of his data, or his participation in a trial facilitated the discovery of a new treatment or increased understanding of a dreadful disease. Insofar as this is so then it might be said to approximate to an informed consent, albeit one which is anticipated, and thus constitute a show of respect for his surrogate autonomy.

Confused elderly patients

120. There are a growing numbers of patients who once enjoyed the capacity to make decisions of all sorts in their lives but who, sadly, are no longer capable of doing so. Various forms of neurological deterioration including Alzheimer's disease rob people of such powers. How can we respect their compromised autonomy in making treatment decisions or other decisions which involve them in health related activities?

121. It would be unethical to take these patients any less seriously than fully competent patients. In approaching decisions concerning them we have much more to go on than we do in the case of neonates. These are people who have lived a full life, whose preferences, values and wishes are probably remembered by some if not many who knew them when well. Their offices should be sought when we reflect on what do to for the patient. They should not be asked to provide proxy consents but rather to help build a picture of the life of our patient in which we can locate the decision that we have to make. Insofar as we are capable of doing this then we might be said to be building a **substituted judgment** about what the patient would consent to.

122. The procedure is well illustrated by the events surrounding the approval of the use of a given patient's case for inclusion in a medical undergraduate curriculum. Susan was in her early fifties. Until just two years

previously she had been a very active professional member of the community. A keen amateur opera singer, a senior science schoolmistress and a wonderful wife of a devoted husband. Then suddenly all began to change. Her memory began to fail and she began to repeat herself having forgotten that she had asked the same question but a few minutes before. Within months conversation became impossible, people were not recognized, ordinary activities were beyond her. She needed constant care for all her needs. Within six months of the onset of her illness she recognised nobody. Hospitalised, she seemed not even to respond to physical stimuli and her joints were rigid. She was painstakingly fed twice a day by her loved ones.

123. At this stage the local medical school was developing a new curriculum and was seeking good cases. In neurology an Alzheimer's case was needed. Susan was identified as the ideal candidate. The family had wonderful recent home movies of her in full health and engaging in her favourite activities. What a graphic portrayal of the ravages of the disease would be provided by the juxtaposition of those images with a video recording of her daily care as currently provided. But how could such a video be made without her consent? How could her autonomy and dignity be respected were she to be involuntarily placed on permanent video record to be gazed upon by successive classes of young students?

124. The case against the proposal seemed overwhelming until her husband came forward to offer the following account of Susan's life. She was an accomplished and enthusiastic teacher who was especially committed to medical education. When well she had been a tireless worker in the community, always putting others before herself. And now there was nothing she could do for learners or for society. Or was there? Yes, there was one last thing. She could be the means of helping young doctors understand something of the human tragedy and the clinical signs of Alzheimer's disease. "If she was given just one minute of lucidity and asked whether she would consent to the film", he said, "she would say 'Yes, Yes, Yes, please make the video recording. It is the last useful thing that I can do for humanity'. The curriculum committee was moved and convinced. The tape was made and has never failed to deeply impress the students. The circumstances of its making are shared with the class to demonstrate that the school teaches informed consent by both precept and example. The tape was shown at her funeral as a tribute. Here was no proxy consent from the husband but a substituted judgment enabling Susan to speak for herself – surely a mark of respect for her autonomy.

Patients with learning difficulties

125. It is important not to confuse intellectual impairment with mental illness. This group of people represents a wide range of intellectual ability and no simple standard of competence can be assumed between them. In each case an assessment according to the criteria outlined above is called for in combination with an awareness of the nature of the decision to be made. Only in extremely serious cases will a person with this problem be unable to make a decision about anything. We do not have the benefit of identifying a life previous to the onset of this developmental condition out of which we shall be able to collect sufficient information to build substituted judgments. Neither do we have the prospect of a growing intellectual maturity which we can anticipate in making a hypothetical judgment about what will be regarded by the person as an acceptable decision. Thus in those cases where either the impairment is so great that the decision is too onerous or complex to be grasped by the person we have to make a best interests judgment on their behalf.

Mentally ill patients

126. As with intellectual impairment so too with mental illness, we cannot assume that all persons in the group are equally competent or otherwise. On the one extreme, people in a psychotic state cannot, by definition, make authentic choices. On the other hand, when not in a florid state, a person with schizophrenia might be quite clear about how he/she feels about matters of life and how he/she would wish to address them. It is the same person with whom we are dealing when he/she is ill and we must endeavour to carry our memory of him/her, when well, into our decision-making procedures on his/her behalf. The same is true of manic depression. When in a manic phase a patient will not always look kindly on apparent interference in his/her commissioning of various actions. But when restored to his/her authentic self that person will be grateful that we took note of the wishes he/she expressed before he/she became ill.

127. The competence of a mentally ill person must be assessed independently of the nature of the decision which he/she wishes to make. Despite reasonableness of outcome being a criterion of competence it is important to acknowledge the possibility of differences in what counts as reasonable between the patient and the clinician.

128. The case of C v Broadmoor Hospital illustrates the matter well. C was a Jamaican immigrant to London soon after the Second World War. He attempted to murder his girlfriend and was sent to Brixton prison. On examination he was diagnosed as a paranoid schizophrenic and removed to Broadmoor Special Hospital. Thirty years later he was still subject to grand delusions and there was little or no prospect of his release. He developed a gangrenous foot and was given only a 15% chance of survival without amputation. The medical personnel recommended him for the procedure as being in his best interests. He refused to lose his leg. It might have been assumed that he was not competent to make such a decision so the case went to court. The court decided that his decision had nothing to do with a failure to understand the prognosis, nor with his paranoia. Rather it took his assertion that 'I would rather be dead with two legs than alive with one' seriously and thought that he was perfectly clear about this. He kept his leg – and he survived. However the latter point was not a vindication of the court's decision for that had nothing to do with C's reason for refusing the surgery.

129. There is a possibility of the reverse confusion occurring when this criterion of competence is strenuously applied. That is, the fact that the outcome of a decision seems so bizarre sometimes leads clinicians not merely to incorrectly establish incompetence but also mental illness. Kevin Wright had two perfectly healthy legs. But he always felt that the left leg was alien to him, not a part of him. He sought help to have the limb amputated. All the surgeons he approached refused and he was recommended for psychiatric treatment, which was all to no avail. He then met a Scottish surgeon who took his story seriously. Satisfied after research that Wright's request was not the expression of a sexual fetish, or a need for dependence or a form of a wish for self-harm he agreed to amputate. The condition has become known as Body Dysmorphic Disorder. More than three years after surgery Wright has claimed that the surgeon has made him complete.

130. Both these examples serve to demonstrate the importance of identifying incompetence independently of simply determining the unreasonable nature of the outcome of a treatment decision.

Unconscious patients

131. Treatment decisions and research activities are often called for in the case of unconscious patients. Should doctors resuscitate? Should they use this or that medication in the early stages of cardiac arrest? These are questions intensive care doctors deal with every day. Clearly their patients are not capable of consenting to or refusing such treatments. Doctors

sometimes have the kind of information referred to in the case of substituted decisions to go on. Relatives are the usual source of this kind of information. *On the other hand, as time is of the essence in these cases, doctors might* not be able to conduct such enquiries and choose to err on the side of life. This can turn out to be a disaster for many survivors whose quality of life is dreadful. Is there any other way in which doctors can preserve respect for the autonomy of such patients?

132. Doctors might at times, and this is likely to become more frequent, have direct access to what seem to be the express wishes of the unconscious patient – then presence of an Advance Directive or a Living Will. Whilst such documents are becoming more popular they carry no legal authority in most places. But they might be the most valuable guide to respect the autonomy of the patient.

133. Such instruments are far from perfect. They have inherent weaknesses which the clinician has to take into account. First they might be old and out of date. How long ago was the wish expressed? Have the patient's views changed over that time? Second, they are hypothetical wishes. They are of the form: if I am found to be in such-and-such a state I will regard that state as worse than death and not wish for any extraordinary means to be used to keep me alive. But we often imagine certain states to be unacceptable which, when they occur, are not so. This explains why so many young people who suffer spinal traumas in sport and their resulting paralyses do not want to be taken off their respirators. Even though before the tragedy they might have regarded such a state as worse than death that is not longer their view. Third, it is necessary to know under what circumstances the documents were produced. Was the person under duress? Was he subject to the pressures of peer groups? The caring doctor with an urgent life-saving decision to make cannot take the piece of paper placed before him as the final word without such facts being established. Thus, whilst he/she would be negligent not to consider the document he/she should not be bound by it.

Oncology patients *(to be further developed)*

134. In the field of oncology there are two different points of view concerning information given to patients and their families. On one side is the more advanced view that tends to give clear and direct information, responding to the need of oncological patients to be well informed about their disease.

135. On the other side there are countries in which the tendency in the field of oncology continues to be that of denying or omitting the negative aspects of the illness in front of the patient, among them the diagnosis itself, sometimes because the patient himself doesn't want to know it. The physician and the other health personnel try to avoid upsetting the patient and involuntarily attacking what is sometimes their most precious possession: hope.

Terminally Ill *(to be further developed)*

Organ's donation *(to be further developed)*

136. Cadaver donors are the most common donors in the western hemisphere. There is no ethical difficulty in utilizing the body, if permission was given by the subject before death. Otherwise we are faced with the problem of ownership of the body and consent. Upon death the person loses his/her rights. In some cultures the relatives retain the rights over the body lost by the deceased by virtue of the affection that previously bound them. This is done as a sign of respect towards the relatives since, strictly speaking, the body doesn't belong to them. Of course, nor does it belong to the doctors that want to use it as a donor.

137. There are two types of legislation concerning consent to organ donation from cadavers:

a) presumed consent: it establishes that every cadaver is a potential donor, except when in life the subject expressly stated the opposite. It is believed this legislation would significantly increase the availability or organs for transplantation. This is in effect in several European countries;

b) expressed consent: it requires the explicit authorization by the subject or, after his death, by the relatives. In some countries the authorization must be in writing and notarized.

III.3 Consent in various categories of contexts

138. While, in theory, the principle of the systematic seeking of informed consent prior to any clinical practice or intervention whatsoever on a patient is universally acknowledged, its effective execution can face operational limits that cannot be ignored.

139. In Western societies, the notions of information and consent of a person to all clinical practices or linked to a research protocol have been *integrated both in legal as well as deontological provisions.* But *even in* these societies it has been seen that the effective implementation of these benchmarks can be confronted with difficulties in certain fields, for example in emergency treatment or certain pathologies (oncology, psychiatry...). Furthermore, different authors have underlined the difficulties in reaching an efficiency of these notions linked to philosophical concepts of benefit or autonomy that can vary according to different schools of thought and evolve over a period of time, resulting in an adaptation of legal and regulatory texts.

140. Developing countries, whilst in tune with these universal principles, are behind in the measures – particularly legal measures – meant to accompany compliance with these principles. Moreover, different constraints, linked to a socio-economical and cultural environment, show the difficulties for these concepts to be put into practice.

141. These difficulties are first of all linked to the conditions of transmitting correct, complete and understandable information to the patient and to the capacity of a patient to fully comprehend this information.

142. Furthermore, the concept of free consent is often defined by the absence of any constraint whatsoever in the choice made by the patient. But while certain sorts of constraints seem obvious and be the object of interdiction – legal or moral – others, just as real, can exist for which it is difficult to advocate a preventive or for that matter repressive action.

III.3.1. Economical context

143. In disadvantaged economical contexts where the demand for treatment is particularly great and where health systems have difficulty in responding adequately, it is possible that there may be difficulties in adhering to or applying the principle of complete information and the systematic solicitation of the consent of a patient in the framework of medical practice in relation to both health-care workers and to patients. Different reasons can be at the heart of these difficulties.

Level of training of medical professionals

144. The health-care system of many developing countries is based on a health care pyramid with the basic level that can range from the infirmary with community health officials, to the health centre with a nurse and, on the top, the element of reference formed by the hospital complex with the different categories of health-care personnel including doctors.

145. It is obvious that with such a distribution the information to be given in the case of health care can be very superficial, even non-existent if the person responsible has only limited training and does not have a full command of the details of this information.

The lack of time for the number of patients

146. In health structures, the personnel is generally understaffed in relation to the demand for care. Whereas in certain European countries there are an average 300 doctors for 100,000 inhabitants, there are 100 times less in certain African countries (1 to 5 doctors for 100,000 inhabitants).

147. Adequate distribution of all necessary information can be difficult even impossible to carry out in the context of a constant work overload.

The lack of means of health-care professionals

148. In a socio-economical context where there is no social coverage for an illness, where means are limited and access to certain therapies problematic, there can be an issue of conscience for a doctor to inform, without this information being able to lead to any action of adequate treatment. This may be the case in certain pathologies, for example, cancer, where the practitioner, in the absence of offering the possibility of appropriate interventions, may have only palliative care to propose. The relevance of dispensing complete information under these conditions may therefore be disputable, added to the fact there exists even in countries that have adequate means, the notion of to what extent a patient can bear information (tolerable truth).

The lack of means of populations for covering their health care

149. In many developing countries, the lack of social provision for health-care coverage and the lack of sufficient revenue lead to a vulnerability before persons likely to enable them to accede to health care. Under these conditions, it can be feared that giving consent is just a means to health care.

150. Furthermore, in certain cases, the lack of confidence in the equity of access to means available can put in doubt the information given and encourage corrupt practices.

151. In light of the reflections above it would appear that the systematic application of the principles of information and obtaining consent is linked to the appropriate qualification of health-care professionals as well as to the presence of material and human resources virtually non existent in such contexts (insufficient number of qualified personnel, mediation personnel, sufficient time, etc.).

III.3.2. The context of populations with a low level of education

Difficult access to information

152. In the context of a low level of education, or illiteracy, it is difficult to give complete information accessible to the patient; simplification of information results sometimes in part of the information being deleted. Sound comprehension of information can moreover become complex when those who intervene do not use the same references in approaching health problems (scientific versus mystic, supernatural).

153. A way of mitigating these difficulties is to encourage information / educational / communication systems through a multisectoral approach in communities, the development of suitable tools to vehicle information, the training of health-care professional to deliver simple, accessible and reliable information.

154. The use of national and local languages is often recommended to facilitate better understanding and can indeed allow populations to have access to at least simplified information. But this recommendation meets operational limits insofar as certain countries are multi-ethnic and consequently there are numerous languages within a country that are not necessarily shared by the health-care professional and the patient. As a result, this language barrier imposes a third party to dispense information, which is not always possible nor always reliable.

155. It should be pointed out that this problem of comprehension of information given by practitioners is sometimes raised in developed countries where illiteracy is not a problem, but due to the complexity and length of documents submitted to patients. Certain authors have in fact underlined the perverse effect of certain jurisprudences resulting in the elaboration of information and consent documents that are very difficult to understand, more destined to protecting the practitioner from being accused of delivering insufficient information rather than to clearly informing the patient.

156. It is therefore necessary to underline the importance of the clarity of the text submitted for signature and its content that should include necessary and sufficient information for the decision to consent or not to consent and this in a language that is accessible to the person concerned. Even more special attention should be given in developing countries.

Difficulties for proving consent

157. In some cases, particularly in situations concerning scientific research, proof of consent is called for. Here again, the implementation of this demand can encounter difficulties, for example:

- in societies of oral tradition, where the value of oral consent cannot be put into question, the demand for proof of the consent in written form can be considered as a lack of trust or even as an insult;
- in illiterate populations, where a sign at the bottom of a page may not reflect a real adherence to the content of the document that is often not or is only partly understood and sometimes creates a suspicion that is difficult to erase.

158. Because of this, even if in principle it is necessary to strive towards the possibility of obtaining written consent, depending on the context, it would be appropriate to explore other ways of providing proof of consent.

III.3.3. Socio-cultural context

The integration of information in social perceptions and religious beliefs

159. Information on the possible risks linked to a clinical practice, in particular if there is a life-threatening risk, is not necessarily perceived as a choice given to the patient to consent or not to an act insofar as life and death are dictated by a superior power and do not therefore depend on this choice. This fatalism can lead to a mechanical acceptance of what is proposed, especially if the trust in the capability and knowledge of the person proposing is total and to the extent that the consequence(s) of these acts that aim to be therapeutic are not assumed to be contingent on this person.

Weight of the community

160. In many societies, the community is the entity where the individual is dissolved and where the decisions of the leaders of the community are not questioned or discussed out of respect due to them because of their age, the wisdom they are supposed to have, and because they are supposed to be the guarantors of knowing what is best for the community.

161. There is a difficulty in aligning the autonomy of individuals that is embodied in Article 5 of the Declaration with certain cultural settings where communal autonomy might be thought to prevail. The expression of an individual wish that goes against these decisions can be difficult or impossible either out of fear of negative consequences for the individual (social disapproval, exclusion...) or out of respect for the leader.

162. Of course, seeking consent from an individual is indispensable even if his/her community is consulted, but the actual value of the consent of an individual, once the community has given its approval, may sometimes provoke questioning.

163. But is it clear that either individual or communal autonomy should be preferred one to another? It depends on the kind of decision which is at stake. For example, as a member of a particular cultural group a person might be approached to engage in a research project or a commercial enterprise which would provide access by the researchers or the business in question to materials or matters which might be seen as belonging to the group rather than to any individual in that group. Sometimes matters of this kind are referred to as traditional knowledge and cultural treasures. It follows that it is not the prerogative of an individual member of that group to profit individually from communal treasures or to betray such privileged knowledge to strangers without the consent of the group. In such cases, such as the exploitation of indigenous flora or fauna, communal autonomy would impose proper limits on individual autonomy.

164. However such cases should not be used as a basis for concluding that cultural considerations can dictate that for members of some groups individual autonomy must always override individual autonomy. For example, if a group is prepared to allow outsiders to carry out research on the community as such, individuals in that community should not be obliged to offer themselves as participants in that research. They might voluntarily devolve the authority to decide for them to the community but this would not undermine respect for their autonomy. This is the import of Article 12 in the Declaration which asserts that respect for cultural diversity and pluralism should not be used to infringe fundamental freedoms nor any of the principles set out in the Declaration, including Article 5.

Decision-making process in the family unit

165. In certain cases, the social structure of many societies in particular in developing countries, especially rural, the distribution of responsibilities and the decisional hierarchy in the family unit are such that the choice to consent or not is not necessarily up to the person concerned. In which case, consent or non-consent, may not reflect the genuine will of the individual but may be a choice imposed by someone else. This may be the case especially for women and children where certain decisions are made by the husband, the father, the mother-in-law, the father-in-law...

166. The child for example, up until a certain age, is not supposed to be endowed with reason and therefore cannot be consulted. This is reinforced by the culture of obedience to parents and especially to the father.

167. The woman concerned by certain decisions that are of direct concern to her or to her child may also be confronted with this decisional hierarchy. Because of this, even if she is consulted as recommended, the consent (or non-consent) given may not reflect her real choice but may be the choice of the person who has the power to decide.

168. It is therefore necessary that the issue of consent be envisaged in a more global context of education and making persons autonomous whilst keeping in mind the primacy of the interests of the person concerned but with due concern to the preservation of the social format.

169. For that, it is necessary to seek alternatives that are adapted but that ensure the respect for the will of the person concerned, and to promote education towards autonomy and individual responsibility.

The authority of knowledge

170. Another aspect that exists in most societies (in both the North and the South) is the absolute trust given to 'those who know' and in particular who distribute health care often present in these societies, to the extent that consent to what is proposed is not a matter for discussion, the argument being: 'Leave it to those who know, they know better than I or my child, my parent etc.'.

171. This aspect is even more acute when it concerns a poor population with a low level of education.

Captive audience *(to be developed)*

IV. Application and promotion

- Reviewing consent and follow-up
- Teaching of information providers
- Communication: process and materials
- Public involvement

V. Executive Summary and Conclusions

- Summary

- Decision tree
- *When should we seek consent?*
  How should we seek consent?
  What should we do when the context makes consent difficult?
  When is the given consent not valid?
  What should 'information' include?
  What about the level and amount of the delivered information
  Delivery of information: when?

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Chapter 4

Speeches at the Thirteenth Session of IBC

- **Mr Koïchiro Matsuura**,
  Director-General of UNESCO
  (opening speech)
- **Mrs Nouzha Guessous-Idrissi**,
  Chairperson of IBC
  (opening speech)
- **Mr Henk ten Have**,
  Secretary-General of IBC
  Director of the Division of Ethics of Science and Technology of UNESCO
  (closing speech)
- **Mrs Nouzha Guessous-Idrissi**,
  Chairperson of IBC
  (closing speech)

I. Mr Koïchiro Matsuura,
Director-General of UNESCO
(opening speech)

Madam Chairperson,
Excellencies,
Ladies and Gentlemen,

It is with great pleasure that I welcome to UNESCO the thirteenth session of the International Bioethics Committee (IBC). I should like to welcome all of you and to thank you for demonstrating by your presence here the importance that you ascribe to UNESCO's activities in the field of bioethics.

Let me first congratulate the Committee's 17 new members, appointed this year, who have already been contributing to its work for the last few months.

I should also like to take this opportunity to congratulate the members of the IBC Bureau elected at the Committee's twelfth session, held in Tokyo in December 2005: the Chairperson, Mrs Nouzha Guessous-Idrissi (Morocco); the Vice-Chairpersons, Mr Leonardo de Castro (Philippines), Mr Gabriel d'Empaire (Venezuela), Mr Eugenijus Gefenas (Lithuania) and Mr David Ijalaye (Nigeria); and the Rapporteur, Mr Claude Huriet (France).

Ladies and Gentlemen,

By adopting the Universal Declaration on Bioethics and Human Rights on 19 October 2005, the Member States of UNESCO hoped to make the principles of human dignity, human rights and fundamental freedoms the very cornerstone of bioethics.

The Declaration, a major step forward in the fields of bioethics and international human rights law, has very quickly become a reference text, as noted recently on two occasions: firstly, when the United Nations was drawing up the international convention for the protection and promotion of the rights and dignity of persons with disabilities and, secondly, when the European Court of Human Rights had to rule on a case relating to the implantation of embryos fertilized *in vitro*.

It was necessary that universal principles be included in international law. However, the law is often merely a starting point that must be followed by explanation, the dissemination of information, awareness-raising, knowledge-sharing, promotion and implementation, which are all indispensable.

The first step, of course, was to translate the Declaration into as many languages as possible so that it could be read by everyone. This has now been done and the text is available in more than 15 languages – a remarkable figure.

UNESCO, for its part, has been working to promote the diffusion of the principles set out in the Declaration and, to that end, to place the question of capacity-building, ethics education, the development of new curricula and the formation of national bioethics committees on the international agenda.

As you no doubt know, UNESCO's Global Ethics Observatory now provides an increasing amount of data on ethics research and education.

Under the Ethics Education Programme, a regional meeting of experts in ethics education was held three weeks ago in Tehran and another regional meeting will take place next week in the Sultanate of Oman. At the beginning of November, a teacher-training course, organized in cooperation with the UNESCO European Centre for Higher Education and the Israel National Commission for UNESCO, was held in Bucharest, Romania, providing one week's intensive training in bioethics to young teachers from Central and Eastern Europe.

Lastly, under the 'Assisting Bioethics Committees' project Member States, in particular developing countries, that so wish, will be assisted in the establishment of national ethics committees. Technical assistance will thus be provided to Malawi, Madagascar and Ghana early next year.

Ladies and Gentlemen,

I now turn to the International Bioethics Committee itself. After concentrating its efforts on drawing up the draft of the Universal Declaration on Bioethics and Human Rights, the Committee can now engage in pedagogical and future-oriented work on the principles set out in the Declaration.

I know that the Committee has decided to concentrate in particular on two sensitive principles in the 2005 Declaration, namely consent and social responsibility.

In regard to consent, we know that it is not always easily applied in practice, especially in emergencies and cases involving organ transplants or involving children or persons with disabilities. I am glad that the Committee is examining this issue and hope that your debates will encourage Member States that so wish to draw up legislation or regulations in that area.

The principle of social responsibility, set out in Article 14 of the Declaration, reflects the need to make bioethics part of open-ended social and political debate by taking a holistic approach to health.

Such an approach, consistent with the Millennium Development Goals, takes into account such vital concerns as access to quality health care, access to adequate food and water, improvement of living conditions and the environment, action to combat marginalization and the reduction of poverty and illiteracy.

Your discussions on the principle of social responsibility will, I hope, prompt and guide discussion by officials and decision-makers in the fields of medicine and life sciences and will address matters of crucial importance to developing countries, such as affordable essential medicines for all.

The Committee will not, of course, duplicate the work or debates on public health policy issues already addressed in other international bodies, in particular the World Health Organization. The point is rather to determine the extent to which the international community and the United Nations system can address those questions from a bioethical standpoint, each contributing its multifaceted experience and expertise.

Ladies and Gentlemen,

As we can see, the issues to be addressed at this session are complex in that they demand a concomitantly technical and global perspective. This is, however, central to the very nature of bioethics: reflection here requires practical medical and scientific expertise combined with a global and social vision of the issues.

I therefore have no doubt that this session will effectively examine these new bioethics subjects in depth, enrich the debate and prepare the ground for future work by UNESCO.

In conclusion, I wish all the members of the Committee, and in particular the Chairperson, Mrs Guessous-Idrissi, a rich and fruitful session. Let me assure you once again of my full and wholehearted support.

Thank you for your attention.

II. Mrs Nouzha Guessous-Idrissi,

Chairperson of IBC

(opening speech)

Mr Director-General of UNESCO,
Dear colleagues, members of the International Bioethics Committee,
Distinguished guests,
Ladies and Gentlemen,

It is a great honour and pleasure for me, in my own name and on behalf of the members of IBC and of the Secretariat of the Division of Ethics of Science and Technology, to welcome you to this thirteenth session of the International Bioethics Committee.

The session opens with a new Committee, following the end of the term of a number of eminent members as required by the Committee's Statutes. Those members made significant contributions to the work of IBC, in particular, to the drafting of the Universal Declaration on Bioethics and Human Rights. Allow me to pay tribute to them once more and to thank them for their contribution.

The session thus begins with a renewed IBC following the appointment of new members, eminent specialists renowned both in their own country and internationally, full of new ideas and energy, ready to take over and, in particular, to contribute to the dissemination and promotion of the principles set out in the Declaration. Allow me here too to congratulate them on their appointment and bid them welcome.

Lastly, this session is opening one year after the adoption by the General Conference of UNESCO of the Universal Declaration on Bioethics and Human Rights, which, like the two previous ones, has rapidly become indispensable in the field of bioethics for the Member States of UNESCO, national and regional law systems and the institutions and committees active in the field. I shall mention in this connection the National Bioethics Advisory Committee of Côte d'Ivoire. After the humanitarian and environmental disaster caused by the scandalous toxic waste spillage in Abidjan in August 2006, the Committee issued a statement in which it

invoked the principles enshrined in Articles 10 (Equality, justice and equity), 13 (Solidarity and cooperation), 14 (Social responsibility and health), 17 (Protection of the environment, the biosphere and biodiversity) and 20 (Risk assessment and management) of the Declaration. It thus referred to these articles in its statement in analysing and making recommendations on the management of the disaster. That attested, if additional proof were needed, firstly, to the reality and relevance of universally acknowledged and applied ethical principles, secondly, to the importance of the existence of national and international ethics bodies and, thirdly, to the leadership role of UNESCO, which has initiated and ensured the adoption of universal instruments on bioethics and has given priority to promoting and assisting ethics committees.

May I now report on the activities carried out by the Committee since its last session.

The IBC's programme of work for the current year was, in accordance with the Statutes, established at its twelfth session, which as you will recall was held in Tokyo. As an ongoing activity, IBC reaffirmed its wish and its members' availability to assist UNESCO in activities aiming to promote and disseminate the principles of the Universal Declaration on Bioethics at the international, regional and national levels. As a result, conferences and seminars have been held in various parts of the world, some publications have been issued and others are in preparation. With this aim in view, rotating conferences organized by the Secretariat in order to publicize IBC, the Intergovernmental Bioethics Committee (IGBC) and UNESCO's work in the ethics of science and technology, in cooperation with or with the assistance of IBC members, were held in New Zealand in March 2006, Peru in April 2006 and Denmark in early November 2006. At the same time, conferences have been organized and/or led on the initiative of IBC members in their respective countries or regions.

The IBC took advantage of holding its twelfth session in Japan and the contributions of many of the region's specialists to discuss the concept of the universality of some principles of bioethics proclaimed by UNESCO in regard to cultural diversity. It emerged that one of the principles for which research, reflection and debate are required is that of **consent**. Based on the principle of individual autonomy, and the assumption that individuals know better than anyone else where their interest lies, the principle of consent has historically been introduced to protect and strengthen the decision-making power of individuals as to their own condition, once they

have been given the requisite information comprehensibly and audibly. The principle of consent is thus generally well accepted by the medical and scientific community. However, its application can be easier in some circumstances than in others, depending on the type of practice, subject or social, economic and cultural context. Further research is therefore required to ensure that a principle proclaimed to be universal can be contextualized and thus be applied universally in circumstances conducive to respect for human dignity, human rights and fundamental freedoms. As the principle is the subject of Articles 6 and 7 of the Universal Declaration on Bioethics, IBC decided, in accordance with its Rules of Procedure, to establish a working group to continue and deepen reflect and debate on the principle in greater depth, and a draft report will be submitted for discussion at the fourteenth session.

Moreover, the Universal Declaration on Bioethics and Human Rights, in addition to affirming principles that are already known and recognized, has broadened the field and scope of bioethics, placing it in the context of open reflection on the biosphere and on the political and social world. The linkage between individual rights and social responsibility thus constitutes the substance of Article 14, which lays down the principle of 'Social responsibility and health'. Furthermore, the discussions on the theme 'Social responsibility: public health and health care' in Tokyo also demonstrated the need for further discussion on that matter. Accordingly, a second IBC working group has been set up. Owing to the complexity of the theme and pursuant to the tradition of open debate in IBC, a proposal on the structure of a report on the matter has been drawn up and will be submitted at this session, followed by the contributions of experts in the field who are here as our guests. There will then be a debate not only among all the IBC members who have gathered here for the session, but also with the audience. I am convinced that we shall be enriched by valuable comments and suggestions made by the participants. It is evident from this approach that IBC gives pride of place to publicity and transparency in its work.

In parallel with these activities, and in my capacity as Chairperson of IBC, I have represented the Committee at various international meetings and forums:

- the Seventh European Forum of National Ethics Committees, which was held on 9 and 10 March 2006 in Vienna, at which I described the process entailed in drawing up the Universal Declaration on Bioethics and Human Rights and its content;

- the Second International Francophone Conference on Bioethics, held in Bucharest from 2 to 4 November 2006, during which I chaired the meeting of French-speaking ethics committees;
- the meeting organized by the World Health Organization (WHO) to address ethical issues raised by the risk of the avian flu pandemic, held in Geneva on 18 and 19 May 2006;
- the meeting in extraordinary session of the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), held in Paris on 27 and 28 June 2006, whose agenda included a feasibility study on the drafting of a 'universal' code of conduct for scientists and other items such as nanotechnology, environmental ethics and ethics education. The next ordinary session will be held in Dakar in December 2006;
- the two meetings of the United Nations Inter-Agency Committee on Bioethics, held on 16 and 17 January and 9 and 10 November 2006 at the World Intellectual Property Organization (WIPO) Headquarters in Geneva and UNESCO Headquarters in Paris respectively. At both meetings the ethical aspects of intellectual property were discussed and a summary report is currently being prepared;
- as Chairperson of IBC, I was invited to sit on the Grand Jury for the 2006 Descartes Prize for Scientific Research, awarded by the European Commission, which met for its deliberations in Brussels from 10 to 12 July 2006. It seems important to me as it shows that the ethical aspects of research are being taken into consideration at all stages: from design to authorization, funding and follow-up, and from there to selection for an international award;
- I was also invited by the Division of Foresight, in the Social and Human Sciences Sector of UNESCO, to take part in the Twenty-First Century Talks which took place on 25 September 2006 at UNESCO Headquarters on the theme 'Knowledge sharing: Forever a future prospect?'. It was an opportunity to state UNESCO's and the IBC's positions on matters of international cooperation and solidarity and on ethical issues of intellectual property, as clearly set out in IBC reports (published in 2001 and 2003 respectively) and in UNESCO Declarations on bioethics;

- lastly, I took part with former Chairpersons and a few former members of IBC and the Secretariat in the meeting convened by the Director-General on 17 October 2006 to prepare for the celebration in 2007 of the tenth anniversary of the Universal Declaration on the Human Genome and Human Rights.

Ladies and Gentlemen,

It is clear from this assessment of the activities carried out by IBC, its members and its Chairperson, which will be supplemented by Mr ten Have's review of the activities of the Division of Ethics of Science and Technology, that bioethics, one of UNESCO's priority programmes, is the subject of increasingly numerous and fruitful initiatives taken by UNESCO of course, with the contribution of IBC and IGBC, as well as other agencies of the United Nations system and other regional and international organizations and institutions.

Furthermore, at all the events that I attended, UNESCO's role as leader in standard-setting action, education, training and assistance to ethics committees was acknowledged and emphasized. This is of course enhanced by the Director-General's personal interest in matters relating to the ethics of science and technology, as may be discerned from his presence at and support for all IBC activities, for which I thank him wholeheartedly. Such effective leadership can only be strengthened by the work and attitude of the members of IBC and the Secretariat and by calm, open and transparent debate with all the institutions, associations and persons active in or concerned by bioethics and its major challenges in regard not only to present generations but also, and no doubt primarily, to the survival of future generations in dignity, peace and security.

Ladies and Gentlemen,

Thank you for your kind attention. I hereby declare open the thirteenth session of the International Bioethics Committee.

III. Mr Henk ten Have,

Secretary-General of IBC
Director of the Division of Ethics of Science and Technology of UNESCO
(closing speech)

Madam Chairperson,
Members of the International Bioethics Committee,
Excellencies,
Ladies and Gentlemen,

The thirteenth session has been an extremely enriching experience, characterized by constructive debate on two of the principles set out in the Universal Declaration on Bioethics and Human Rights. This shows that UNESCO's standard-setting action cannot, and must not be regarded as an end in itself, but as a catalyst for new debate, shared reflection and action at the international, regional and local level.

IBC – faithful to its mandate and its role as a multidisciplinary, multicultural and pluralist forum for exchange and dialogue – has once again known how to address difficult and sensitive questions, both traditional and new, and meet genuine ethical challenges that face society today, in both developed and developing countries.

In the course of the session, IBC re-examined the issue of consent and took note of important, pertinent and critical commentaries and opinions, as well as constructive criticism concerning the draft report, which I am sure will be put to good use in its future work of refining, revising and completing the document presented to you.

The same may be said of the debates on the theme 'Social responsibility and health': the IBC's work on this issue is certainly at a less advanced stage than its work on the principle of consent, which goes to show that we are embarking on a new, and by nature global, debate that echoes the United Nations' concerns, as reflected in the Millennium Development Goals, which approach health from the same global and social angle.

The thirteenth session, which has been an opportunity to continue the reflection initiated in Tokyo less than a year ago, has above all enabled the IBC's working group on the theme to share its thoughts, concerns and questions with the intellectual community present here.

There is still much ground to be covered and a great deal of work to be done: IBC will focus on that endeavour, drawing on its members' expertise and on contributions from UNESCO's partners, both inside and outside the United Nations system, without which the Organization's efforts would be in vain.

Ladies and Gentlemen,

In the last few years, the need for ethical reflection to be coupled with – and even precede – scientific developments has been keenly felt. Owing to that sudden realization by the international community, UNESCO has made the ethics of science and technology, in particular bioethics, one of its priorities and has made efforts to define and promote universal principles founded on shared ethical values in order to guide such scientific and technological development and the attendant social transformations.

As a result of that very realization, after intensive standard-setting action, UNESCO now concentrates on activities to promote and disseminate the principles adopted and to encourage their implementation regionally and nationally, namely capacity-building in bioethics and education and raising the awareness of decision-makers, specialists and the general public as the primary targets of UNESCO's action in that regard.

The holding of the next session of the IBC in 2007 on the African continent (in Kenya) is perfectly in keeping with this approach: everyone knows how central the African countries are to the ethical issues raised by the development of science and technology and to what point Africa has a role to play internationally in the debate on ethics.

Ladies and Gentlemen,

Allow me to conclude by extending thanks once more, on behalf of the Director-General, to the members of the International Bioethics Committee for their contribution, individually and as a committee, to the Organization's work and to all the participants in the thirteenth session who, by gathering here today, have vindicated UNESCO's choice of the path on which it embarked more than ten years ago.

Thank you.

IV. Mrs Nouzha Guessous-Idrissi,

Chairperson of IBC

(closing speech)

We have now come to the end of the thirteenth session of the International Bioethics Committee after long hours of debates and group discussions on two topics that are equally complex and important, namely social responsibility and health, and consent.

While the principle of social responsibility seems at first sight difficult to define given its cross-cutting character, its determinants and its economic, social, cultural and political repercussions, that of consent is just as difficult, primarily because autonomy, vulnerability, free choice, decision and responsibility are relative concepts. That stood out clearly not only in the presentations and the documents, on which the discussions were based, but also in the debates themselves.

How, then, can it all be summed up?

Social responsibility in health is perforce a topical issue owing to the health situation in the world and its prospective trends, as the various statistics provided have shown. For, despite the scientific advances achieved in the fields of knowledge and resources for diagnosis and health care, the situation is not only failing to improve at the global level but also seems to be causing more inequalities and inequities, which raises the ethical issue of access for all to the benefits of scientific and medical progress. It is this ethical dimension that must guide the working group's future work in drawing up the report on the subject. In other words, it must take an ethical approach to the various health determinants, in particular, in identifying the main ethical issues that all actors must take into account in discharging their responsibilities (the international community, States, governments and political stakeholders, health care and research institutions and professionals and related professional associations, companies producing and marketing therapeutic instruments, and citizens).

Ultimately the report, which will of course be addressed primarily to States, could also be used to build awareness and education for all, thereby ensuring better health and quality of life throughout the world.

Furthermore, as this involves a very broad and multiple-entry principle, the working group will discuss, as suggested, the desirability of drawing up the report in several stages and the possibility of concentrating initially on questions directly related to the ethics of access to health care.

In regard to the issue of consent, the intensity of the discussions and the broad range of questions and concerns raised during yesterday's and today's debates have highlighted not only the difficulties of applying this principle but also differences in people's understanding and experience of this fundamental principle in bioethics, not in terms of its meaning but rather *its real or supposed consequences. I am therefore of the view that* IBC's report should:

- explore further the question of individual autonomy, which is **a right** enshrined in the Universal Declaration of Human Rights, and **not a privilege**, which can nevertheless be limited:
  - in the interests of public health,
  - on account of the vulnerability of some patients;
- distinguish the right to information which includes the right not to know;
- study in greater depth the question of arrangements for obtaining consent taking into account the cultural context, and stress its non-instantaneous or final character since it is a process of responsible and objective dialogue, thus opening up the possibility of refusal or withdrawal of consent, as stated clearly in the version of the declaration issued by IBC;
- differentiate situations involving clinical practice from those involving research practices, as is the case in Article 6 of the *Universal Declaration on Bioethics and Human Rights*;

I do not think that the report will address all situations requiring special consent to research, since it would in any event be incomplete.

To conclude and to explain in a constructive manner the remarks that I made in qualifying my impression that yesterday's debates had portrayed consent as a burden or a trap, I wished to stress that:

- Material or cultural conditions may not and must not be invoked to challenge a principle recognized to be a universal principle. Every *effort should be made to find appropriate means of ensuring that it is* not infringed, in accordance with Articles 12 (Cultural diversity) and 26 (Interrelation and complementarity);
- the principle of consent, which is regarded by some as an application tool for applying the principle of autonomy rather than as a principle *per se*, must reflect a responsible partnership between the doctor or the researcher and the patient, which necessarily presupposes mutual confidence. The choice is not merely between paternalism and mistrust. Rather, it is a culture of responsible dialogue that must be promoted to ensure that consent is experienced less as a burden and continuous, objective, benevolent and unselfish dialogue on the part of the doctor that will make consent less of a trap.

It is obvious that although the working groups had already produced serious bases for the discussions, the debates in this room in the last two days have shown the extent to which IBC is, and will continue to be, a forum for debate among its members and with all those who are interested and concerned.

I shall now end by thanking you all – the members and chairpersons of working groups, chairpersons of meetings, members of IBC, the Secretariat, the observers and the participants in the session – for your valuable contributions which will be duly taken into account in the IBC's future work.

I also thank the interpreters and the technicians who have made it possible for us to hold this session in a comfortable and very convivial atmosphere.

I declare the thirteenth session of IBC closed.

Chapter 5

COMPOSITION OF IBC IN 2006-2007

NAME	TERM OF OFFICE
AMIRASLANOV **Prof. (Mr) Ahliman** (Azerbaijan) Rector of the Azerbaijan Medical University Head of the the University Oncology Clinic at the City Cancer Center Member of the Azerbaijan Academy of Sciences	2006-2009
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Chapter 6

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Part II

‘SOCIAL RESPONSIBILITY AND HEALTH’

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- **Mr (Dr) Emilio La Rosa Rodriguez** (Peru)

THE RIGHT TO ENJOY THE BENEFITS OF SCIENTIFIC AND TECHNOLOGICAL PROGRESS AND ITS APPLICATIONS[1]

M. (Prof) William A. Schabas,
Professor of Human Rights Law
Director, Irish Centre for Human Rights
National University of Ireland, Galway

I feel very honoured to present the results of some on-going research that I have been doing in cooperation with the UNESCO Human Rights Section. We will be holding a two-day expert meeting on this issue in June of next year, I believe in The Netherlands, co-sponsored by UNESCO, the Centre for Human Rights in Ireland and the International Law Centre in Amsterdam.

I shall begin with a little quotation because this is all about progress :

Progress, man's distinctive mark alone,
not God's, and not the beasts.
(Robert Browning, *A Death in the Desert.* 1864)

The idea of progress appears only rarely in international human rights sources. It ought to be more prominent. What we are doing and what we are striving for should have something to do with 'progress'. Those of you who are familiar with the legal instruments might recall that the idea of progress appears in Article 2 of the International Covenant on Economic, Social and Cultural Rights. It is the idea that States should implement economic, social and cultural rights progressively in keeping with their levels of development. It almost has a pejorative sense for those who apply and interpret international human rights law, because of the suggestion that somehow this lack of progress can be an excuse to States for not implementing human rights to their fullest extent.

I am going to start in this discussion of the right to benefit from scientific progress with the most recent provision, Article 15 (Sharing of benefits) of the Universal Declaration on Bioethics and Human Rights, which as you know was adopted only a year ago.

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1. Nicolas Rouleau and Edel Hughes assisted in the research on this article.

Article 15 – Sharing of benefits

The text of this article is derived from a previous instrument adopted in 2003, the International Declaration on Human Genetic Data. The texts are virtually identical, except that the more recent provision, the text of 2005, is more general in its scope and application.

But the idea has been around for a long time and if we want to trace the origin of these two provisions, particularly Article 15 of the Universal Declaration on Bioethics and Human Rights, we have to go back to 1948, here in Paris and the adoption of the Universal Declaration of Human Rights.

Article 27 of the Universal Declaration of Human Rights says that everyone has the right to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits. This is the part of the Universal Declaration of Human Rights that is repeated and developed in Article 15 of the Declaration. I think that Article 15 of the Universal Declaration of Bioethics and Human Rights will in effect come to be seen to a large extent as an attempt to develop Article 27 paragraph 1 of the Universal Declaration of Human Rights. The provision is a mysterious one; it is one that comes at the very end of the Universal Declaration of Human Rights, which might suggest to some that it was an afterthought, that it is not very important, that it is not very significant. And the fact is that it has suffered from a great deal marginalization over history.

Article 27 of the Universal Declaration of Human Rights was codified subsequently in a treaty. The Universal Declaration of Human Rights was a resolution of the General Assembly of the United Nations and it set out principles. But it says in its preamble that it is a common standard of achievement, and many have argued that it was not meant to create binding legal norms. That job was left for a subsequent treaty, one that, in the early days of the Cold War, was sliced into two treaties, the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. Article 27 of the Universal Declaration of Human Rights was transformed into a treaty provision, Article 15 of the International Covenant on Economic, Social and Cultural Rights:

> Article 15
>
> 1. The States Parties to the present Covenant recognize the right of everyone:
>
> (a) To take part in cultural life;
>
> (b) To enjoy the benefits of scientific progress and its applications;

(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields.

In paragraph 1 sub-paragraph (b) we see that the States parties recognize the rights of everyone to enjoy the benefits of scientific progress and its applications. It is essentially the same provision as what we find in Article 27 of the Universal Declaration of Human Rights.

To give you the chronology, the Universal Declaration was adopted by the General Assembly, sitting here in Paris at the *Palais de Chaillot*. This was before the United Nations established its Headquarters in New York. The General Assembly used to meet in different parts of the world, and thus the Universal Declaration of Human Rights was adopted here in December 1948. The two International Covenants were adopted in December 1966 although the provisions that they contain were developed over the years between 1948 and 1966, and mainly during the 1950s. The text of Article 15 was debated and finally adopted by the United Nations General Assembly in 1957. At the time there were two issues in the debate. The first was the possibility of abusive use of science, a matter related to issues about the development of what we now call weapons of mass destruction, of nuclear weapons in particular. There was a concern that human rights adopt a position on the direction scientific progress should take. But those ideas are not reflected in the text, essentially because of difficulties in reaching sufficient consensus on that idea.

The other issue, and this is reflected in both the Universal Declaration of Human Rights and in the International Covenant on Economic, Social and Cultural Rights, concerns intellectual property. Paragraph 2 of Article 27 of the Universal Declaration of Human Rights recognizes the right to protection of the moral and material interests resulting from any scientific, literary or artistic production of which a person is the author. There is a similar provision in Article 15 of the International Covenant. And what these two texts have done is create a tension between the idea that there is a universal human right to benefit from scientific progress and the idea that the author or inventor has the right to ownership over his or her creation. I

think all of you can understand how that has led to a great deal of debate and an unsettled interpretation of exactly what Article 27 of the Universal Declaration of Human Rights means. I believe that this tension continues to the present day, although there is no explicit reference to this in Article 15 of the UNESCO Universal Declaration of 2005. But undoubtedly discussions about the scope of the right to benefit from scientific progress involve addressing, and taming, this difficult issue of the protection of intellectual property.

The idea of the protection of the right to benefit from scientific progress was repeated again in the Vienna Declaration and Programme of Action of 1993. The Vienna Declaration is, you might say, the contemporary statement of human rights that corresponds to the Universal Declaration of Human Rights. It was adopted at the Conference on Human Rights in Vienna in 1993 and it repeats in one of its paragraphs that everyone has the right to enjoy the benefits of scientific progress and its applications:

> Everyone has the right to enjoy the benefits of scientific progress and its applications. The World Conference on Human Rights notes that certain advances, notably in the biomedical and life sciences as well as in information technology, may have potentially adverse consequences for the integrity, dignity and human rights of the individual, and calls for international cooperation to ensure that human rights and dignity are fully respected in this area of universal concern

As you can see, the Vienna Declaration gives a very clear biomedical slant to the norm which had not been present in the previous writings and texts on the subject. The Vienna Declaration refers explicitly to advances notably in biomedical and life sciences and also to information technology and it notes that they may have potentially adverse consequences for the integrity, dignity and human rights of the individual.

The Vienna Declaration and Programme of Action of 1993, which is a document representing a consensus of the international community, adopted at a conference of the United Nations, brings the focus of the right set out in Article 27 of the Universal Declaration of Human Rights squarely into the issues that concern the International Bioethics Committee. Probably when the Universal Declaration of Human Rights was adopted, most people did not even know what the term biomedical even meant. But the Universal Declaration of Human Rights is the kind of instrument whose interpretation evolves over time, and that is what it is doing in this area, with useful contributions from such instruments as the Vienna Declaration of 1993.

Audrey Chapman observed quite bluntly, in research paper for the Committee on Economic, Social and Cultural Rights (2000), 'the human rights community has neglected Article 27 of the Universal Declaration of Human Rights and Article 15 of the International Covenant on Economic, Social and Cultural Rights'. If you look at other sources – such as resolutions of the General Assembly and of the Commission on Human Rights (recently abolished, and replaced by the Human Rights Council) as well as academic writings on the Universal Declaration and the Covenants, you will see how accurate her observation is. Article 15 of the recent UNESCO Declaration shines a little light onto this long-neglected human right. We may hope that it will revive interest in the subject, while at the same time provide the opportunity to inject more substantive content into the right itself, which is, after all, still only a shell waiting to be filled, a blank page awaiting our interpretation.

With regard to the new relevance of the norm, I would suggest aspects *where our interest should now be focused. First of all, globalisation in general* is something that bring out the problems associated with the right of everyone to benefit from scientific progress. There are, of course, enormous global disparities in terms of benefiting from scientific progress and I don't need to elaborate on them in any great detail. But this conflict or tension between the protection of intellectual property and the right to benefit from scientific progress has become extremely important. The issue also arises in the question of protection of the know-how or the intellectual property of *indigenous peoples in terms of the priorities of research. If everyone has the* right to benefit from scientific progress do we also have a right to determine the direction that scientific research should take? And finally there is the problem that preoccupied the drafters of the norm back in the 1940s and 1950s, which is the abusive use of sciences.

First, let me address what are known as the trade related aspects of intellectual property, something involved in intellectual property law refers to as TRIPS. There has been some development on this with respect to the intellectual property protection of certain drugs, particularly anti retroviral drugs. At the Doha negotiations of the World Trade Organization there were some important concessions made to enable less-developed countries not to have to pay exorbitant prices that were allegedly justified in the name of providing proper financial incentives for scientific research in the North. This has manifested itself in debates within some of the major human rights institutions within the United Nations. Some important thinking on this has gone on within the Sub-Commission on Human Rights, which continues to

exist as a subordinate body of the Human Rights Council. Not long ago, at one of the final meetings of the Commission on Human Rights, United States delegate said that any challenge to the validity of internationally agreed protection of intellectual property rights would be bad public health policy. What he was doing was answering those who set up the right of everyone to benefit from scientific progress against the idea that intellectual property benefits from some absolute protection.

With respect to indigenous peoples, the latest version of the draft declaration on the rights of indigenous peoples recognizes the right of indigenous peoples to control over their intellectual property. The Declaration was adopted by the Human Rights Council in June, after some two decades of negotiation. Article 31 is the relevant provision:

> 1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.
>
> 2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.

There is a famous case of a remedy that was part of the traditional medicine of an aboriginal group in the Amazon. Some French researchers learned it from the aboriginal group, studied it and took it back to France, got a patent on it and out of misguided courtesy to the aboriginal group they named the drug after it. The indigenous peoples were not amused, and did not appreciate the fact that the company was making a lot of money out of something they had developed as part of their own culture and that was part of their collective intellectual property. Well, one might argue that this is sharing the benefits of scientific progress with the rest of the world. Obviously, it has to be reconciled in some way with the rights of indigenous peoples.

The right to benefit from scientific progress also engages with other economic, social and cultural rights. It involves research priorities. I alluded to this earlier. It seems to me that when one adopts a rights-based analysis, if there is a right to benefit from scientific progress there is an argument to be made that we also have an interest and a right to the direction that scientific research takes. That would mean that scientific research ought to be directed towards diseases of the South such as malaria and tuberculosis, and perhaps not as much to diseases of the North such as hypertension and obesity.

Secondly, this would engage with research priorities with respect to food. Major multi-national corporations in this field have developed genetically-modified species which are then treated by genetically-modified pesticides and herbicides and ultimately create a permanent dependence of farmers on those crops. Here is a case where research in the development of food and of products that are necessary to create it, are being distorted in the interests of maximizing profit for corporations. I think that here there are also important arguments based on the universal right to benefit from scientific progress that can be brought to bear.

A word then about protection from abuses of human rights. I think I've said enough on patent protections and intellectual property, except to note of course that no only can a monopoly of certain products deprive parts of the world, for financial reasons, of scientific progress, intellectual property protection in many ways can also prevent scientific progress. I am not arguing here for the abolition of patent protections or of intellectual property regimes. But I want to argue that factoring in the human right to benefit from scientific progress can blunt the more disastrous effects of some of the other legal regimes that we have.

And finally there is the issue of the orientation of science towards plainly destructive uses that are contrary to the interests of humanity – development of weapons of mass destruction. There is in fact a very interesting discussion to be had about so-called 'humanitarian weapons'. As we all know from reading the newspapers, in armed conflicts these days the combatants boast about how they are using 'smart technology' in order to minimize the danger of collateral damage and of the threats that weaponry can cause to civilian populations. I learned about a very perverse example of how this works in a meeting in the United Kingdom a few years ago where we discussed the weaponry that was used in the Gulf War in 2003. We were told by a senior official from the British Defence Department that in fact one of the problems with these 'smart weapons', and he gave some examples of sophisticated cluster bombs and so on, is that when armies go to war now, yes, they have these sophisticated weapons that are designed to minimize civilian causalities. These included things like anti-personnel mines and cluster bombs that have little bits of metal embedded in the pieces so that they can be located afterwards. That way, you can clean up a battle field, especially when the battlefield happens to be a city where people live. But when these armies go to war, and they ask the quarter master to give them bombs, the quarter-master behaves like the merchant in a market. He wants to use up the oldest stuff first. There is a

'sell-by' date on weapons, and that means the oldest ones in stock, which may not necessarily be the most humanitarian ones – indeed, this is likely – are the ones to be used first. I think this is one of the intriguing examples of a failure to benefit from scientific progress because armies are using the most primitive and the least humanitarian of their weapons simply because they want to use them up before their expiry date.

The right of everyone to enjoy the benefits of scientific progress and its applications, set out in Article 27(1) of the Universal Declaration of Human Rights and Article 15(1) of the International Covenant on Economic, Social and Cultural Rights, has been relatively neglected. Its adoption was uncontroversial. The drafting history reveals an inherent tension, from the beginning, between enjoyment of the benefits of scientific progress and the protection of intellectual property. This issue has taken on great importance in recent years with the globalization of intellectual property regimes, as expressed in mechanisms like the TRIPS Agreement of the World Trade Organization. Throughout the human rights systems, great concerns have been expressed about such issues as the development of medications for 'neglected diseases', the virtual unavailability of the most modern medications because of the high prices associated with patent monopolies, and the perversion of biomedical and biotechnology research agendas in the interests of the bottom line of transnational corporations. The relationship between the right to enjoy the benefits of scientific research and the protection of intellectual property has become a touchstone within the larger debate about the effects of globalization on the promotion and protection of human rights.

The norm set out in Article 27(1) of the Universal Declaration and Article 15(1) of the Covenant has a great deal of unexploited potential. Its universal acceptance, as reflected in the drafting history of the two provisions, makes it especially useful, and promises great effectiveness. Moreover, on reflection, it seems to be intricately linked with the entire philosophy that underlies the rights enshrined in the Covenant, namely, progressive realization of the right to food, to medical care, to education, to housing and so on. Freedom from want will be achieved in part by a fairer distribution of resources, and by international cooperation, but it will also result from scientific progress. Given its obvious significance, it is quite striking how rarely the norm is actually invoked. The reports of the relevant special rapporteurs, and the resolutions of such bodies as the Commission on Human Rights, the General Assembly and the Sub-Commission on the Promotion and Protection of Human Rights, only make rare references to

the provisions protecting the right to enjoy the benefits of scientific progress. Perhaps greater attention will also enhance, more generally, the role of the much neglected fifth category, 'cultural rights', which include the right to benefit from scientific progress, within the overall scheme of protection of international human rights.

HEALTH AND SOCIAL RESPONSIBILITY IN THE WORLD ACCORDING TO THE UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS: ANALYSIS BY MEANS OF COMPOSITE INDICES

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SUMMARY

Social responsibility in health may be defined as the commitment of societies and their institutions to individual and collective health. The indicator of this social responsibility is a health development index that can be used for monitoring and evaluating governments' commitment levels in health. This quantitative indicator offers a useful alternative to a simple indicator since it is made up of several variables telling us about four important dimensions: infant mortality, vaccination, access to medical care and public expenditure on health care. The indicator of social responsibility in health (IRSS) analysis has permitted the classification of countries within three levels: countries possessing a high social responsibility level (IRSS ≥ 0.800), countries with a medium level (0.500 to 0.790) and countries with a low social responsibility level (IRSS ≤ 0.490).

The health situation in these different countries reflects their degree of social responsibility in health, as we can see from the strong correlation between the above-mentioned levels and the health indicators taken into account.

The average figures for the latter are lower among countries with a low social responsibility level, but they become higher when the degree of social responsibility in health increases.

Article 14 of the Universal Declaration on Bioethics and Human Rights recognizes health to be a fundamental right and proposes that access to health care and medicines be favoured with no discrimination on the basis of ethnic background, religion and social class.

The international health situation is nevertheless still precarious. We would like this social responsibility in health indicator to serve as a tool for following up and evaluating recommendations given by international organizations in health matters. This is indeed the function we are trying to give this indicator.

I. Social responsibility in health

Taking into account the spirit of the Universal Declaration on Bioethics and Human Rights and the notion that health is determined by a series of factors, social responsibility in health is defined as the commitment of societies and their institutions with respect to individual and collective health, given that health – but above all sickness – transcends rigid geographical limits, affecting people's dignity and physical and psychological integrity.

Clearly, solutions to world health problems can only come from a global effort (medical and health globalization).

Indicator of social responsibility in health (IRSS) and other indices

The IRSS[1] may be regarded as an indicator of a country's development and commitment with respect to health. This quantitative indicator is not without certain limitations because the concept of social responsibility in health is much broader and cannot be fully gauged by means of this indicator.

It nevertheless offers a useful alternative to a simple indicator since it is made up of variables providing information on four important dimensions:

- mortality, through the infant mortality rate;
- preventive action, through the vaccination indicator. This indicator comprises three variables: measles vaccination rates; DTP (diphtheria-tetanus-pertussis) coverage (3 doses); and poliomyelitis coverage (3 doses) in one-year-old infants;
- access to health care: rate of deliveries assisted by qualified health personnel;
- the State's commitment in health: public expenditure on health as a percentage of GDP.

1. La Rosa E., Dubois G., Tonnellier F., La responsabilité sociale en santé. A propos de la Déclaration Universelle sur la Bioéthique et les Droits de l'homme. Submitted for publication to *La Revue de santé publique*, October 2006.

The IRSS and the other indicators have been constructed along the lines of the method used by the United Nations Development Programme (UNDP) to calculate the Human Development Index (HDI) [(2)].

The other indicators providing information on maternal and infant mortality, vaccines, nutrition, access to mother and child care, access to clean water and sanitation, and public expenditure on education and health are:

- indicator of maternal and infant mortality (IMMI). It consists of three variables: infant mortality, mortality of under-five-year-olds and declared maternal mortality;
- indicator of vaccination (IV). This is calculated on the basis of three indicators of vaccination in one-year-olds: DTP 3 doses, measles and poliomyelitis 3 doses (%);
- indicator of nutrition (IN), based on two indicators: percentage of low-weight newborns and percentage of moderate or serious weight insufficiency in under-five-year-olds;
- indicator of access to mother and child care (IAMI), based on two variables: prenatal care coverage rate and deliveries assisted by qualified personnel;
- indicator of access to clean water and adequate sanitation (IAAPSA), based on two variables: percentage of population using improved sources of clean water and percentage of population using adequate sanitation facilities;
- indicator of public expenditure on health and education (IGPSE), based on two variables: public expenditure on health (% of GDP) and public expenditure on education (% of GDP).

II. The world situation

<u>Level of social responsibility in health according to the IRSS</u>

On the basis of IRSS analysis, countries can be placed in three categories (Table 1):

1. countries with a high level of social responsibility, comprising 49 countries with an IRSS ≥ 0.800;

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2. United Nations Development Programme, Human Development Report. New York: UNDP, 2005.

2. countries with a medium level of social responsibility, whose IRSS ranges between 0.500 and 0.790, comprising 77 countries; and
3. countries with a low level of social responsibility, corresponding to 39 countries with an IRSS ≤ 0.490.

The averages for the other indicators studied maintain a certain correlation with the levels of social responsibility in health (Table 2). A low IRSS level, for example, thus goes with the lowest averages for the other indicators.

This strong correlation between the degree of social responsibility in health and the global health situation is also to be found between the UNDP Human Development Index (HDI) and the IRSS ($R = 0.91$ $p < 0.001$).

Health situation

The degree of social responsibility in health is very clearly reflected in the state of health in each of the countries examined, which points to a direct relationship between these two factors. For example, countries with low IRSS levels are marked by a precarious state of health, as is mainly the case in Africa and Asia (Table 3).

A survey of particular regions leads to the conclusion that the health situation is more precarious in sub-Saharan Africa, South-East Asia and the Pacific Zone (Table 4). Within the African continent, however, the health situation is much more serious in some regions, as in Central, East and West Africa (Table 5).

On the subject of social responsibility in health, it is important to observe that 69% of African countries are at a low IRSS level and that the gap between them and the ideal maximum value (Figure 1) is greater in the countries of Central and East Africa (0.59 and 0.58 respectively). Where continents are concerned, the biggest gap is that of Africa (0.34), three times greater than that of Europe (0.16) and twice as wide as that of the Americas (0.26).

III. Social responsibility in health and the Universal Declaration on Bioethics and Human Rights

The Universal Declaration on Bioethics and Human Rights recognizes that 'health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors' and considers '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'.

However, as seen above, the degree of social responsibility in health gauged by means of the IRSS is still deficient in many countries: 32% of countries have an IRSS below 0.600 and the ideal value is still a long way from being attained in many countries of the African continent.

On the other hand, the Declaration recognizes, in Article 14, that health is a fundamental right and proposes that access to health care and medicines be advanced without distinction as to race, religion and economic or social condition. What the article proclaims is still at a remove from reality however, as shown by the indicator of mother and child care (IAMI), which is deficient in several world regions, particularly in East Africa (IAMI = 0.45) and West Africa (IAMI = 0.60). This difficulty of access to health care has more serious consequences in the case of vulnerable population sectors, like children and expectant mothers, as shown by the maternal and infant mortality indicator, which is much lower in countries with problems of access to health care. The link between access to health care and mortality has been described in the report of the World Health Organization (WHO) on the effectiveness of health systems in 191 countries[3].

As to access to adequate nutrition and water, as prescribed in Article 14, paragraph 2(b) of the Declaration, such access is still very much wanting in a great many countries, particularly in Africa. The lowest indicators of nutrition (IN) are to be found in East Africa (0.46) and West Africa (0.50). It is estimated that more than 800 million individuals lack access to sufficient nutrition in quantity and quality, and that over two billion suffer from deficiencies of micronutrients, such as vitamin A, iodine and iron.

Each year nearly 11 million children under the age of five die, and practically all these deaths occur in developing countries, three quarters of them in sub-Saharan Africa and southern Asia. These two regions also have the highest rates of hunger and malnutrition (33 and 24% of the total population, respectively).

These scourges constitute the underlying causes of more than half of child mortality. Hunger and malnutrition are the decisive factors in the deaths of around six million children each year[4]. These children do not generally die of hunger but rather of an aggregate infection. Most of these children would not die if their immune system were not weakened by hunger and malnutrition.

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3. WHO, Health systems: improving performance. Geneva: WHO, 2000.
4. FAO, The State of Food Insecurity in the World. Roma: FAO, 2005.

This situation is still far from being resolved, as shown by the gaps existing between the average IN for Europe, the other continents and especially the regions of East and West Africa (Figure 2).

The prime cause of mortality in the world is the lack of clean water and sanitation, which indirectly kills some eight million individuals annually through water-borne diseases (cholera, typhoid, diarrhoea, etc.). In Africa, the indicator of access to adequate clean water and sanitation (IAAPSA) is the lowest of all continents (0.49) and, regionally speaking, the lowest averages are to be found in Central and East Africa (0.39).

At present, 1.4 billion inhabitants lack access to clean water and 2.6 billion (42% of the world's population) are without any access to a basic sanitation system (sewage collection and treatment). The United Nations estimates that around 1.6 million lives could be saved each year with an improvement in conditions of access to clean water and to sanitation and public hygiene services[(5)].

The World Water Council[(6)] estimates that, at the very least, it is necessary to double present funding in order to halve the percentage of the population without access to clean water by 2015 and so meet one of the Millennium Development Goals. About $10 billion a year is needed to pay for a minimum service of access to clean water and sanitation for populations lacking such amenities, and between $15 and $20 billion more to maintain existing services. However, annual funding in the sector is between $14 and $16 billion, maintenance included, not counting the cost of sewage treatment[(7)].

With respect to medicines, many countries are faced with problems of access in quantity and quality. UNDP[(8)] estimates that, in 14 countries of sub-Saharan Africa, less than half of the population has permanent access to affordable essential medicines. Likewise, in malaria-affected African countries, only 45.6% of children under five running a high temperature are treated with antimalarial medicines, and the proportion is lower in East Africa (21.8%). The problem is much more serious in the case of a mortal

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5. UNESCO, World Water Report, Water: a shared responsibility. Paris: UNESCO, 2006.
6 World Water Council, Triennial Report 2000-2003, WWC, 2004.
7. Camdessus M., Report of the World Panel on Financing Water Infrastructure. Marseille : WWC, 2003.
8. UNDP, Human Development Report, 2003.

sickness such as HIV/AIDS since access to antiretroviral treatment and medical care for AIDS victims is still limited. Five to six million people in low- and middle-income countries need antiretrovirals immediately[9]. It is also the case that this difficult access to medicines cannot be attributed solely to economic problems but is also due to a lack of effective distribution networks. In general, health services often lack essential medicines owing to a whole array of administrative, logistical and economic difficulties.

Since the establishment of the World Trade Organization (WTO) and the signing of the TRIPS agreements (trade-related aspects of intellectual property rights), because patent protection enables the pharmaceutical industry to impose its price, the developing countries have been confronted with a rise in the cost of basic medicines. Another serious problem is the cross-resistance of some pathogenic germs to existing medicines and the scant effort being made to discover new medicines to treat certain common diseases in the poor countries of the southern hemisphere. Most noteworthy is the industry's lack of interest in research to develop new vaccines and medicines for tropical diseases and ailments typically affecting the poor sectors of the population. One explanation is the high cost of research and the prospect of little or no profit from marketing the products.

The Doha Declaration (November 2001) recognizes that the TRIPS agreements must not be an obstacle to the protection of public health and access to medicines for all. A degree of flexibility is therefore accepted in the event of a public health crisis, particularly with respect to the HIV/AIDS epidemic, tuberculosis, malaria and other epidemics[10]. After the Doha Declaration, the WTO Executive Council adopted a resolution in January 2002 guaranteeing access to essential medicines.

However, the pharmaceutical industry has an industrial and commercial logic frequently at odds with the public health goals of the developing countries faced with such epidemics as AIDS, malaria, tuberculosis, and perhaps also at odds with some recommendations of the Universal Declaration on Bioethics and Human Rights, since the high price of the medicines puts them practically beyond the reach of the world's poor populations.

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9. UNAIDS, Report on the global AIDS epidemic, 2004.
10. World Trade Organization WT/MIN(01)/DEC/2: Declaration on the TRIPS agreement and public health, adopted on 14 November 2001.

The pharmaceutical industry argues that the high price of the medicines is justified by the very high cost of research and development of new medicines. At present, the average cost of a new medicine is $1.25 billion ($359 million in 1990 and $700 million in 1997). However, the research and development cost of an 'orphan' medicine (fewer than 200,000 patients) is very much lower. This difference has to do with the cost of promoting the medicine (Phase 4 of clinical trials), which comes under the heading 'research and development cost'. The purpose of Phase 4 is often to accustom the doctor to prescribing a new medicine. 'Orphan' medicines do not need expensive promotion campaigns given the limited number of patients. On the other hand, new medicines do call for costly promotion and marketing to impose the new medicine in the market, particularly if it is a medicine offering but a modest therapeutic advance.

Table 1. Classification according to IRSS, 2006

	High IRSS	55	Bahamas	111	Lesotho
1	Germany	56	Oman	112	Bolivia
2	Sweden	57	Mongolia	113	Azerbaijan
3	Norway	58	Chile	114	Vanuatu
4	Denmark	59	Brunei	115	Philippines
5	France	60	Uruguay	116	Togo
6	Japan	61	Rep. of Korea	117	Indonesia
7	Czech Republic	62	Brazil	118	Bhutan
8	Portugal	63	United Arab Emirates	119	Gambia
9	Cuba	64	Mauritius	120	Malawi
10	United States	65	Albania	121	Guatemala
11	Australia	66	Qatar	122	Swaziland
12	Netherlands	67	Saudi Arabia	123	Benin
13	Croatia	68	Malaysia	124	Comoros
14	Belgium	69	Mexico	125	Eritrea
15	Canada	70	Grenada	126	Tajikistan
16	Slovenia	71	Singapore		**Low IRSS**
17	Hungary	72	Sri Lanka	127	Ghana
18	Finland	73	El Salvador	128	Senegal
19	Israel	74	Tunisia	129	Sudan
20	Slovakia	75	Suriname	130	Mauritania
21	Panama	76	Lebanon	131	Uganda
22	Luxembourg	77	Iran	132	Mozambique
23	New Zealand	78	Libya	133	Gabon
24	United Kingdom	79	Trinidad and Tobago	134	Myanmar
25	Macedonia TFYR	80	Jamaica	135	Zambia
26	Belarus	81	Syria	136	Djibouti
27	Costa Rica	82	Turkey	137	Timor-Leste
28	Poland	83	Guyana	138	Cameroon
29	Dominica	84	Algeria	139	Kenya
30	Ireland	85	China	140	Burkina Faso
31	Tonga	86	Uzbekistan	141	Rwanda
32	Barbados	87	Venezuela	142	Cambodia
33	Lithuania	88	Viet Nam	143	India

34	Colombia	89	Maldives	144	Madagascar
35	Bulgaria	90	Kyrgyzstan	145	Guinea
36	Estonia	91	Belize	146	Guinea-Bissau
37	Romania	92	Armenia	147	Nepal
38	St Vincent and the Grenadines	93	Solomon Islands	148	Bangladesh
39	Argentina	94	Fiji	149	Papua New Guinea
40	Sao Tome and Principe	95	Turkmenistan	150	Mali
41	Austria	96	Cape Verde	151	Yemen
42	Jordan	97	Botswana	152	Dem. Rep. of the Congo
43	Latvia	98	South Africa	153	Côte d'Ivoire
44	Ukraine	99	Kazakhstan	154	Pakistan
45	Moldova	100	Paraguay	155	Haiti
46	Antigua and Barbuda	101	Egypt	156	Ethiopia
47	Bahrain	102	Namibia	157	Equatorial Guinea
48	Russia	103	Ecuador	158	Burundi
49	Bosnia and Herzegovina	104	Dominican Rep.	159	Angola
	Medium IRSS	105	Nicaragua	160	Laos
50	Cyprus	106	Honduras	161	Sierra Leone
51	Saint Kitts and Nevis	107	Georgia	162	Central African Rep.
52	Kuwait	108	Morocco	163	Chad
53	Saint Lucia	109	Peru	164	Niger
54	Thailand	110	Zimbabwe	165	Nigeria

Source: E. La Rosa

Table 2. Levels of social responsibility in health and average of other indicators

IRSS	IDH* p ± et	IMMI* p ± et	IV* p ± et	IAMI* p ± et	IN* p ± et	IAAPSA* p ± et	IGPSE* p ± et
Low	0.46 ± 0.01	0.52 ± 0.17	0.53 ± 0.21	0.48 ± 0.20	0.44 ± 0.17	0.42 ± 0.15	0.21 ± 0.10
Medium	0.71 ± 0.11	0.84 ± 0.13	0.85 ± 0.14	0.84 ± 0.13	0.72 ± 0.14	0.72 ± 0.16	0.33 ± 0.14
Upper	0.86 ± 0.08	0.97 ± 0.05	0.94± 0.06	0.96 ± 0.76	0.85 ± 0.07	0.92 ± 0.14	0.52 ± 0.11
Total	0.69 ± 0.18	0.81 ± 0.20	0.81 ± 0.21	0.76 ± 0.23	0.66 ± 0.20	0.68 ± 0.24	0.38 ± 0.17

* *p < 0.0001*

Table 3. IRSS and other indicators by continent

	IRSS* p ± et	IMMI* p ± et	IV* p ± et	IAMI* p ± et	IN* p ± et	IAAPSA* p ± et	IGPSE* p ± et
Africa	0.49 ± 0.16	0.59 ± 0.21	0.65 ± 0.25	0.63 ± 0.20	0.57 ± 0.15	0.49 ± 0.19	0.31 ± 0.14
Asia	0.66 ± 0.17	0.82 ± 0.18	0.86 ± 0.17	0.73± 0.30	0.62 ± 0.25	0.67 ± 0.23	0.27 ± 0.16
Oceania	0.67 ± 0.19	0.87 ± 0.10	0.62± 0.28	0.74 ± 0.29	0.63 ± 0.18	0.65 ± 0.26	0.44 ± 0.13
America	0.74 ± 0.11	0.91± 0.07	0.86 ± 0.15	0.87 ± 0.14	0.78 ± 0.09	0.84 ± 0.13	0.41 ± 0.16
Europe	0.84 ± 0.07	0.97 ± 0.03	0.93 ± 0.07	0.96 ± 0.06	0.88 ± 0.05	0.92 ± 0.13	0.49 ± 0.14
Total	0.67 ± 0.19	0.81 ± 0.20	0.81 ± 0.20	0.76 ± 0.23	0.66 ± 0.20	0.68 ± 0.24	0.38 ± 0.17

* *p < 0.0001*

Table 4. IRSS and other indicators in various regions

Region	IRSS*	IMMI*	IV*	IAMI*	IN*	IAAPSA*	IGPSE*
Sub-Saharan Africa	0.47	0.58	0.64	0.59	0.50	0.48	0.28
Pacific	0.60	0.85	0.57	0.58	0.63	0.61	0.42
South-East Asia	0.61	0.84	0.79	0.68	0.56	0.57	0.23
Lat. Am. & Caribbean	0.73	0.90	0.85	0.87	0.78	0.83	0.40
East Asia	0.80	0.91	0.92	0.93	0.77	0.73	0.46
Eastern Europe	0.82	0.96	0.98	0.99	0.91	0.89	0.42

* $p < 0.0001$

Table 5. IRSS and other indicators in Africa and in OECD countries

Region	IRSS*	IMMI*	IV*	IAMI*	IN*	IAAPSA*	IGPSE*
Central Africa	0.41	0.49	0.44	0.63	0.60	0.39	0.17
East Africa	0.41	0.60	0.67	0.45	0.46	0.39	0.31
West Africa	0.42	0.47	0.58	0.60	0.50	0.45	0.26
Southern Africa	0.55	0.64	0.73	0.73	0.59	0.54	0.36
North Africa	0.64	0.81	0.81	0.73	0.74	0.70	0.38
OECD	0.87	0.98	0.92	0.96	0.84	0.97	0.54

* $p < 0.0001$

Figure 1. Gap between average IRSS and maximum value

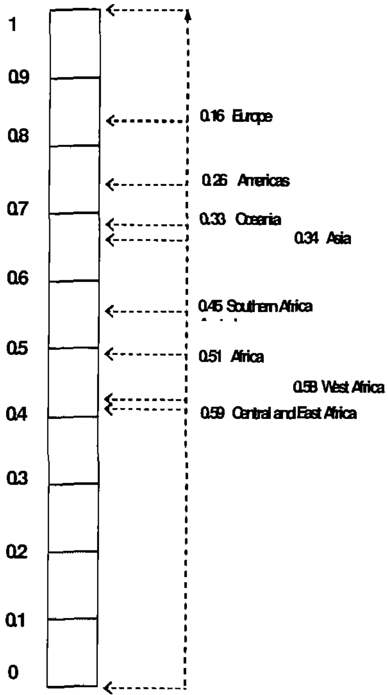

Figure 2. Gap between average IN and maximum value