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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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Table of Contents

Introduction .................................................................................................................. 1

PART I

CHAPTER 1
Report of the Twelfth Session of the International Bioethics Committee of UNESCO (IBC)
(Rapporteur : Claude Huriet) .................................................................................. 5

CHAPTER 2
Universal Declaration on Bioethics and Human Rights .......................... 21

CHAPTER 3
Speeches at the Twelfth Session of IBC ......................................................... 33

I. His Imperial Highness the Crown Prince ........................................... 35

II. Mr Koïchiro Matsuura,
    Director-General of UNESCO
    (opening speech) ......................................................................................... 37

III. Mrs Michèle S. Jean,
    Chairperson of IBC
    (opening speech) ......................................................................................... 43

IV. Mr Kenji Kosaka,
    Minister of Education, Culture, Sports, Science and Technology of Japan
    (opening speech) ......................................................................................... 47

V. Mr Yoshiaki Ishizawa,
    President of Sophia University, Tokyo, Japan
    (opening speech) ......................................................................................... 49

VI. Mrs Michèle S. Jean,
    Outgoing Chairperson of IBC
    (closing speech) ........................................................................................ 51
VII. Mrs Nouzha Guessous Idrissi,
Chairperson elect of IBC
(closing speech) .............................................................. 55

VIII. Mr Pierre Sané,
Assistant Director-General for Social and Human Sciences
Representative of the Director-General of UNESCO
(closing speech) .............................................................. 57

IX. Mr (Prof.) Tomosuke Kasuya,
Professor at the Faculty of Law,
Sophia University, Tokyo, Japan
(closing speech) .............................................................. 61

CHAPTER 4
Composition of IBC in 2004-2005........................................ 63

CHAPTER 5
Liste of Participants in the Twelfth session of IBC ............... 69

PART II

The Diversity and Universal Norms on Bioethics: How does Japan Handle Bioethical Issues? Keynote Address
Mr (Prof.) Taizo Yakushiji ................................................. 97

SESSION I
“UNESCO AND UNIVERSAL PRINCIPLES IN BIOETHICS: WHAT’S NEXT?”
Déclaration universelle sur la bioéthique et son suivi - Diversité dans l’universalité. Conférence magistrale
M. (Prof.) Ryuichi Ida ...................................................... 107

UNESCO and Universal Principles in Bioethics: What’s Next?
Mme Michèle S. Jean ...................................................... 115

UNESCO and Universal Principles in Bioethics: What’s Next?
Mr (Justice.) Michael Kirby .............................................. 121

UNESCO and Universal Principles in Bioethics: What’s Next?
Mr (Prof.) David Adedayo Ijalaye .................................... 137
SESSION II

“UNESCO DECLARATIONS IN THE FIELD OF BIOETICS AND CULTURAL DIVERSITY”

Unity and Diversity in Nature: Movement and Identity in Human Beings Keynote Address
Mr (Prof.) Patricio Ventura Juncá ...................................................... 153

UNESCO Declarations in the Field of Bioethics and Cultural Diversity. Keynote Address
Mr (Prof.) Tomoaki Tsuchida.............................................................. 163

Les Déclarations de l’UNESCO en matière de bioéthique et la diversité culturelle : l’exemple du Maroc
Mme (Prof.) Nouzha Guessous Idrissi .............................................. 167

UNESCO Universal Declaration on Bioethics and Human Rights: Why There is a Need to Take Cultural Diversity into Account
Mr (Prof.) Michel Revel...................................................................... 175

Universalité et diversité culturelle dans la Déclaration universelle sur la bioéthique et les droits de l’homme
M. (Dr) Roberto Andorno .................................................................. 185

SESSION III

“INFORMED CONSENT”

Is Consent always the Appropriate Concept?
Mrs (Prof.) Sheila McLean................................................................. 193
Informed Consent: Implementation Challenges
Mr (Prof.) Eugenijus Gefenas ................................................................. 197

Informed Consent
Mrs (Prof.) Regine Kollek .................................................................... 201

Informed Consent
Mrs (Prof.) Heloisa Gonçalves dos Santos ......................................... 203

Informed Consent: Current Status in Clinical and Research Settings in Japan
Mr (Dr) Tadafumi Kato ........................................................................ 207

SESSION IV
“SOCIAL RESPONSIBILITY: PUBLIC HEALTH AND HEALTH CARE”

Social Responsibility: Public Health and Health Research
Mr (Prof.) Adolfo Martinez-Palomo ...................................................... 215

Social Responsibility and Health Care Consent
Mr (Prof.) Hans Galjaard .................................................................... 225

Social Responsibility: Public Health and Health Care
Mr (Dr) Yasuhiko Morioka .................................................................... 231

SESSION V
“CONTEMPORARY PROBLEMS OF BIOETHICS ASIAN PERSPECTIVES”

Cultural Diversity in Bioethics
Mr (Prof.) Renzong Qiu ....................................................................... 239

Demystifying the Human Genome, Bioethics and Human Rights
Mr (Prof.) Chog-Lek Koh ...................................................................... 241

Bioethics and Japan
Mrs (Prof.) Satoko Tatsui ..................................................................... 243
Providing an Asian Character to the Globalization of Bioethics
Mr (Prof.) Leonardo De Castro .......................................................... 247

Some Issues on Implementation of International Bioethics Declarations in Vietnam Practice
Mr (Prof.) Luong Le Dinh ................................................................. 249

Bioethical Concerns in a Muslim Country – Pakistan
Mr (Prof.) S. Qasim Mehdi ................................................................. 251

Contemporary Problems of Bioethics and Its Internationality: An Asian Paradigm
Mr (Prof.) Prakash Narain Tandon ..................................................... 257
INTRODUCTION

At the kind invitation of the Government of Japan, the twelfth session of the International Bioethics Committee (IBC) took place at Sophia University in Tokyo, Japan, from 15 to 17 December 2005, gathering together more than 250 participants from some 40 countries.

This twelfth session was organized around the Universal Declaration on Bioethics and Human Rights, adopted by acclamation by the General Conference of UNESCO at its 33rd session, on 19 October 2005. In accordance with the agenda, the session provided an opportunity to envisage ways of disseminating and implementing the principles of the Declaration as well as deepening reflection on three of them: cultural diversity, informed consent, and social responsibility and health care.

One session was also devoted to Asian perspectives on contemporary bioethical issues, allowing an exchange of views on the different approaches taken in Asia to practical bioethical issues.

These Proceedings comprise, in a first part, the report of the session, the Universal Declaration on Bioethics and Human Rights, the speeches delivered at the opening and closure of the session, as well as the composition of IBC for 2004-2005 and the list of participants in the session.

In a second part, they comprise, in their original language, the presentations of speakers (or their abstracts) during the different working sessions.
PART I
I. Introduction

1. At the kind invitation of the Government of Japan, the twelfth session of the International Bioethics Committee (IBC) was held at Sophia University in Tokyo, from 15 to 17 December 2005, bringing together more than 250 participants from some 40 countries.

2. In accordance with the agenda (see Annex, page 18), the twelfth session was organized around the Universal Declaration on Bioethics and Human Rights, adopted by acclamation on 19 October 2005 by the 33rd session of the General Conference of UNESCO. This session provided an opportunity to envisage ways of disseminating and implementing its principles as well as deepening reflection on three of these: cultural diversity, informed consent, and social responsibility and health care.

3. One session was also devoted to Asian perspectives on contemporary bioethical issues, allowing an exchange of views on the different approaches taken in Asia to practical bioethical issues.

4. During the meetings reserved for members of the Committee, IBC elected a new Bureau for 2006-2007 (a Chairperson, four Vice-Chairpersons and a Rapporteur) and finalized its programme of work (see section VIII).

5. The twelfth session also saw the official launch of the Global Ethics Observatory (GEObs), an information portal freely accessible online to all Member States and the general public. The observatory consists of databases on experts, institutions, education programmes and legislation in the sphere of ethics, and as such, contributes to the dissemination of the principles set out in the Declaration, by providing Member States – academics...
and civil society as well as governments – with a valuable reference tool and a comparative resource hub of ethics activities throughout the world.

II. Opening of the twelfth session of IBC(1)

6. His Imperial Highness Prince Nahurito honoured the opening ceremony of the twelfth session of IBC with his presence. A number of scientific and political personalities from the host country also attended the ceremony, including Mr Kenji Kosaka, the Japanese Minister of Education, Culture, Sport, Science and Technology (MEXT) and Mr Yoshiaki Ishizawa, President of Sophia University.

7. In his welcoming remarks, his Imperial Highness Prince Nahurito said that he was delighted to welcome the twelfth session of IBC to Tokyo. Although scientific and technological progress had been beneficial to humanity by helping to improve the quality of life, he believed that it was crucial to look at scientific and technological research and development and its applications from an ethical point of view. He also considered that it was essential to deal with ethical issues not only at the individual level of researchers and societies, but also within a framework of international cooperation.

8. In his opening address, the Director-General of UNESCO, Mr Koïchiro Matsuura, thanked the Japanese Government for its hospitality and expressed his delight at seeing an IBC session held in Asia for the first time. He then referred to the Universal Declaration on Bioethics and Human Rights, the result of two years of concerted effort by IBC, governmental experts and the Secretariat. He thanked IBC and its Chairperson for their hard work throughout the elaboration of this instrument. He recalled that UNESCO, following an intense normative phase, was now going to focus its energy on awareness-raising and dissemination of the principles set out in the Declaration. The twelfth session therefore provided an opportunity to concentrate on the future of the Declaration and on ways of disseminating and applying its principles. The Director-General concluded his address by warmly thanking the outgoing members of the Committee for their dedication to the work of IBC.

1. All the addresses delivered during the session, as well as all the interventions, are reproduced in these Proceedings.
9. After thanking the Japanese Government and Sophia University for the effort which had gone into preparing the twelfth session, Ms Michèle S. Jean, Chairperson of IBC, emphasized the importance of this particular IBC session, the first since the adoption of the Declaration. She considered that the Declaration reflected a pragmatic consensus between all points of view, by virtue of the cooperation of all participants, and a transparent and inclusive procedure. By requesting the elaboration of such a Declaration, Member States had shown visionary spirit in responding to ethical issues raised by scientific and technological developments and by global problems, such as access to health care. She concluded by remarking that the time had now come to focus on implementing the UNESCO Declarations in the field of bioethics, something to which IBC could undoubtedly make a major contribution.

10. Mr Kenji Kosaka began his opening address by stressing that greater international cooperation was required in the field of bioethics, due to the transnational nature of research activities in life science. The Japanese government calls upon a panel of experts in bioethics from the Council for Science and Technology Policy (CSTP), to assist it with the preparation of national legislation and guiding principles on bioethical issues. The recently adopted Universal Declaration on Bioethics and Human Rights would no doubt serve as a basis for the elaboration of future legislative texts. Mr Kosaka considered that this session, held just after the adoption of the Declaration, would be extremely important for providing guidance on the application of the principles it set out.

11. Mr Yoshiaki Ishizawa said that he was honoured and gratified to be able to welcome the twelfth session of IBC to his university. Given the vast number of ethical issues raised by rapid developments in life science over the past few years, he considered that the Universal Declaration on Bioethics and Human Rights constituted a major event, making way for a new era in bioethics. The Declaration would no doubt become a guide to a better future at all levels, in particular social. Finally, he expressed a wish for this session to be a source of open and constructive discussion and intellectual debate.

12. Mr Taizo Yakushiji, Executive Member of the Council for Science and Technology Policy of Japan, then gave a keynote address on ‘Diversity and Universal Norms in the field of Bioethics: How does Japan Handle Bioethical Issues?’ during which he provided an assessment of bioethics in Japan, in particular at the legislative and institutional levels. Mr Yakushiji began by identifying three major subjects: stem cell research and embryos, organ transplants and animal testing. He then gave a
presentation of the Japanese Council for Science and Technology Policy (CSTP), chaired by the Prime Minister, whose main areas of reflection are life science, nanotechnology, environmental science, and information and communication technology. The Council is composed of different groups of experts, one of which works specifically on bioethics. Among other things, the panel of experts on bioethics has elaborated guiding principles on the treatment of the human embryo within the framework of the law relating to the regulation of human cloning techniques and other similar techniques, which came into force in 2001.

III. UNESCO and universal principles in bioethics: what’s next?

13. Session I, entitled ‘UNESCO and universal principles in bioethics: what’s next?’ was co-chaired by Mr Patrick Robinson, Judge at the International Criminal Tribunal for the former Yugoslavia and Vice-Chairperson of IBC, and Mr Saku Machino, Professor at Sophia Law School, Sophia University, Japan. During this session, reflection on possible follow-up to the Universal Declaration on Bioethics and Human Rights centred on two main areas: firstly, the dissemination and implementation of its principles, and secondly, its evolution.

14. The session opened with a keynote address given by Mr Ryuichi Ida, Professor at the Graduate School of Law of Kyoto University and former Chairperson of IBC (1998-2002), and presentations were then given by the following speakers: Ms Michèle S. Jean, Chairperson of IBC, Mr Michael Kirby, Justice of the High Court of Australia and member of IBC; Mr David Adedayo Ijalaye, Emeritus Professor of International Law at Obafemi Awolowo University (Nigeria) and member of IBC; Mr Héctor Gros Espiell, Ambassador of Uruguay to France and UNESCO and member of IBC; and Mr Mohammad Hamdan, Senior Advisor at the Arab Open University of Riyadh, Saudi Arabia and member of IBC.

15. With regard to the implementation of the Declaration, it was recalled that the Declaration is a non-binding instrument setting out general principles. It falls to the States to incorporate these principles into national law in order to give them effect. Therefore, States bear primary responsibility for their implementation, both at the national level (Article 22) and within the international community (Article 24).

16. Discussion was prompted by questions relating to the interpretation of principles worded in a general manner. In particular, some participants expressed concern over possible exceptions to which no reference
is made in the text of the Declaration. It was recalled that limitations on
the principles as a whole are provided for and defined by Article 27 of the
Declaration. Moreover, as the Declaration is part of the declaratory corpus
of UNESCO, it should be interpreted and applied in conjunction with the
Universal Declaration on the Human Genome and Human Rights (1997)
and the International Declaration on Human Genetic Data (2003). Finally,
it was also recalled that, as an instrument of international law, the articles
of the Declaration could only be interpreted according to international law
and could not under any circumstances be subject to provisions made in
national law that were not consistent with international law.

17. Emphasis was also placed on the importance of developing activities
that would foster the widest possible dissemination of the Declaration and
raise awareness among the majority of people, in particular by ensuring
that the text is translated and published in the greatest possible number of
Member States’ official and national languages. Similarly, it was consid-
ered extremely important to set up educational activities encouraging, for
example, the incorporation of the principles of the Declaration into school
teaching curricula.

18. In connection with this point, the Secretary-General of IBC referred
to two activities launched by UNESCO with the aim of fostering public
awareness of bioethical issues and ethics education: firstly, GEObs (see
para. 5), secondly, the Ethical Education Programme (EEP), which aims to
encourage and support Member States in elaborating curricula for ethics
education, by providing them with assistance, not only in promoting ethics
programmes, but also in setting up infrastructures and identifying the nec-
essary resources.

19. With regard to the evolution of the Declaration, some participants
envisaged the possibility of instigating a procedure of approval by the
United Nations General Assembly – following the example of the Universal
Declaration on the Human Genome and Human Rights in 1998 – to allow it
to gain a high profile on the international political scene.

20. Reference was also made to advances in science and technology and
to social changes that will inevitably lead to new developments in bioethical
reflection. As such, it is foreseeable that the text of the Declaration may be
re-examined in a few years’ time, to ensure that it remains abreast of new
reflection on the subject. Some even raised the possibility of making the
Declaration binding, once the debate has matured and if this is thought to
be necessary.
IV. UNESCO Declarations in the field of bioethics and cultural diversity

21. Session II was co-chaired by Mr Pierre Sané, Assistant Director-General of UNESCO for Social and Human Sciences, and Mr Takayuki Morisaki, Director of the Department of Bioscience at the National Cardiovascular Centre of Japan and member of IBC. This session sought to examine how the notion of cultural diversity could tie in with the universal principles set out in the UNESCO Declarations in the field of bioethics.

22. The session began with two keynote addresses given by Mr Patricio Ventura Juncá, member of the Governing Council of the Pontificia Academia Pro Vita (Holy See), and Mr Tomoaki Tsuchida, Professor at the School of Human Sciences of Waseda University (Japan). It then continued with presentations by Ms Nouzha Guessous-Idrissi, Researcher and Consultant on human rights and bioethics and Vice-Chairperson of IBC; Mr Michel Revel, Professor of Molecular Genetics at the Weizmann Institute of Science (Israel) and member of IBC; and Mr Roberto Andorno, Research Fellow at the Centre for Ethics at the University of Zurich (Switzerland) and member of IBC.

23. The debate initially focused on the duality of notions of universality and cultural diversity: these should not be opposed, but handled in a complementary and balanced way. Mention was made of the UNESCO Universal Declaration on Cultural Diversity of 2001, to which IBC made constant reference during the process of drafting the Universal Declaration on Bioethics and Human Rights.

24. A number of speakers stressed the need to avoid the pitfalls of monocentrism in the attempt to fill the scientific and technological gap between developed and developing countries. Bioethical reflection must take into account and respect cultural diversity, while remaining committed to ensuring that a principle has universal scope before it is affirmed.

25. Some participants referred to values specific to certain cultures, to which it appeared to be difficult to attribute a universal character. The status given to the individual in the community varies greatly from one culture to another, especially between Western countries – where the individual appears to take precedence over the community – and Asian countries – where the family or group still has considerable influence on individual decision-making. Issues relating to the beginning and the end of life are also bound up with inherently cultural values on which universal consensus appears problematic for the moment.
26. The Universal Declaration on Bioethics and Human Rights aims nonetheless to establish a certain number of universally recognized and accepted principles. It stipulates that cultural diversity must be respected in so far as this does not infringe human dignity, human rights and fundamental freedoms, nor the principles set out in the Declaration, nor limit their scope. A balance must therefore be found between universality and diversity. The Declaration sets out core principles that must be upheld by all, while allowing for variation in the ways in which they are implemented from one culture to another. For example, although the principle of consent is now a well-established principle in bioethical debate, the form that it may take – written, verbal, etc. – has to be envisaged according to the cultural context.

V. Informed consent

27. Session III was co-chaired by Mr Claude Huriel, Professor of Medicine and President of the Administrative Council of the Institut Curie (France), Rapporteur of IBC, and Mr Kiyoshi Aoki, Emeritus Professor at Sophia University and President of the Japanese Association for Bioethics. In the course of this session, practical issues arising from case studies were presented to demonstrate how the concept of consent, although recognized in bioethics, still requires more extensive debate and reflection, in the light of recent scientific and technological developments and cultural characteristics specific to our societies.

28. The following speakers gave presentations: Ms Sheila McLean, Director of the Institute of Law and Ethics in Medicine of the University of Glasgow (United-Kingdom); Mr Eugenijus Gefenas, Professor of Biomedical Ethics at the University of Vilnius (Lithuania) and member of IBC; Ms Regine Kollek, Professor of Health Technology Assessment at the University of Hamburg (Germany) and member of IBC; Ms Heloisa Gonçalves dos Santos, Director of the Medical Genetics Service at the St Maria Hospital in Lisbon (Portugal) and member of IBC; and Mr Tadafumi Kato, Group Director of the Ageing and Psychiatric Research Group at the RIKEN Brain Science Institute of Saitama (Japan).

29. The debate took as its starting point the generally acknowledged fact that, although informed consent is recognized as a fundamental principle in many texts, it is not always easy to apply in practice. Attention was drawn to several practical situations in which the conditions of gaining informed consent might vary: cases of treatment and medical diagnosis for therapeutic and non-therapeutic ends, cases of invasive and non-invasive treatment,
cases of ‘routine’ medical practice, cases of research affecting a given population, etc.

30. The application of the principle of informed consent is strongly linked to developments in the doctor-patient relationship. One barrier to implementing the conditions of consent as stipulated by the Declaration – free, informed and express – is the traditionally paternalistic nature of this relationship, as a result of the Hippocratic Oath. Although major development has been seen in certain countries, the basic question is how to minimize the extent of the patient’s vulnerability during the consent procedure, so as to re-establish an egalitarian relationship between doctor and patient. Some considered that the principle of informed consent ought to be a transposition of the principle of patient autonomy and of the responsibility of the doctor (or researcher).

31. The modern model implies a direct doctor-patient relationship where family members are considered third parties and where the patient’s autonomy is therefore better respected. This model conflicts with the traditional tripartite model, where the patient’s family has an important role to play in the doctor-patient relationship.

32. Some participants made reference to issues bound up with economic and social pressure, which often make it difficult to gain consent in the best conditions. However, everyone agreed that these problems were beyond the scope of bioethics and touched on broader, global problems.

33. Finally, emphasis was placed on the need to develop activities intended to educate not just the public, but also medical and scientific bodies, if the principle of informed consent is to be applied as effectively as possible. Training in this subject should be encouraged.

VI. Social responsibility: public health and health care

34. Session IV, devoted to the theme of ‘Social responsibility: public health and health care’, co-chaired by Ms Michèle S. Jean, Chairperson of IBC, and Mr Shigetaka Asano, Professor at the School of Science and Engineering at Waseda University (Japan), provided a forum for debate on one of the innovative principles of the Universal Declaration on Bioethics and Human Rights, set out in Article 14.

35. The session was punctuated with three presentations by the following speakers: Mr Adolfo Martinez-Palomo, Director-General for Research at the National Institutes of Health (Mexico) and member of IBC; Mr Hans Galjaard, Emeritus Professor of Human Genetics at the University Hospital Rotterdam (Netherlands) and member of IBC; and Mr Yasuhiko Morioka,
Emeritus Director of the Japanese Red Cross Medical Centre and Chairman of the Medical Ethics Committee of the Japanese Medical Association.

36. In the course of the debate, all contributors remarked that the Declaration opened up the perspective of a new agenda for bioethics by giving it greater importance and broadening its scope to include global problems. The question was to what extent and from what angle bioethics should tackle these issues.

37. The gap between developed and developing countries in the sphere of public health and health care continues to widen, despite remarkable global economic growth and marked improvement in living conditions across part of the planet, due to scientific and technological developments. Some considered the gap to be the result of a market which does not take into account the principles of justice and equity. Bioethics may have a role to play in fostering greater awareness of the moral duty to make substantial financial provision for public health and health care.

38. Some participants added that owing to the coexistence in developing countries of so-called ‘ancient’ pathologies – such as tuberculosis or malaria – and contemporary pathologies – such as depression – a long-term health policy should be developed and implemented at the national level, in addition to international cooperation. This would entail not just financial but also human investment, for example, with regard to training and educating health-care professionals.

39. From a purely scientific point of view, and in parallel with any actions carried out in the sphere of public health, it was also considered urgent to involve scientists in developing countries in all research linked to new technologies, so as to prevent the gap between countries widening still further.

40. The issue of the implications of this new bioethical agenda for the action of IBC, particularly in the light of Article 14 of the Declaration, was raised. Some were of the opinion that the Committee should now devote part of its work to these issues, with a view to deepening reflection on the notions of ‘social good’ and ‘social responsibility’ in the sphere of health.

VII. Contemporary problems of bioethics – Asian perspectives

41. Session V concentrated on ‘Contemporary problems of bioethics – Asian perspectives’ and was co-chaired by Mr Donald Evans, Professor of Philosophy, Director of the Bioethics Centre at the University of Otago (New Zealand) and member of IBC, and Mr Yutaka Hishiyama, Director for
Scientific Affairs of the Science Council of Japan. It was divided into two parts.

42. The first part of the session was devoted to sensitive issues in Asian bioethics. It was introduced with a keynote address by Mr Kiyoshi Kurokawa, President of the Science Council of Japan, and followed by presentations from Mr Sung-Yo Cho, Former Professor at Sung Shin Women's University (Republic of Korea); Mr Qiu Renzong, Professor at the Institute of Philosophy of the Chinese Academy of Social Science (People's Republic of China); Mr Chog-Lek Koh, Associate Professor at the National Institute of Education of Nanyang Technological University (Singapore); and Mrs Satoko Tatsui, Associate Professor at the International Graduate School of Social Science of Yokohama National University (Japan).

43. The second part looked at various Asian perspectives on bioethics and was illustrated with presentations by the following IBC members: Mr Leonardo De Castro, Professor of Philosophy at the University of the Philippines; Mr Luong Le Dinh, Professor and Head of the Laboratory of Molecular Genetics at Vietnam National University; Mr S. Qasim Mehdi, Professor of Molecular Biology and Medical Genetics at Karachi University (Pakistan); and Mr Prakash Narain Tandon, Emeritus Professor at the Department of Neurosurgery of the All India Institute of Medical Sciences (India).

44. Attention was drawn to a number of cultural values shared by Asian countries, which need to be taken into account in implementing the Declaration. One of the fundamental differences between Asian and Western countries lies in the role played by family and community in individual decision-making. For example, in Japan, this means that a family has the right to refuse organ removal. Similarly, in some cultures, the concept of human life is not limited to the individual, but also encompasses animals and plants, or the entire ecosystem.

45. The debate also turned to the illicit traffic in organs that affects many Asian countries. All contributors condemned organ trafficking, invoking the principle of non-commercialization of the human body and its parts. Some were of the opinion that alternative solutions to a straightforward ban, such as the possibility of compensation by health services, would need to be envisaged in the search for a more effective response to the problem, particularly in the most disadvantaged countries. Moreover, reference was made to Article 21 paragraph (5) of the Universal Declaration on Bioethics and Human Rights, which stipulates that ‘States should take appropriate measures, both at the national and international levels, to combat bioterror-
rorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials’.

46. Otherwise, questions were asked about the controversy caused by the oocyte donation affair in the Republic of Korea. As part of stem cell research carried out at the laboratory of Mr (Prof.) W.S. Hwang, some of the women who worked there supplied oocytes in return for financial reward, something which runs counter to the principle of non-commercialization of the human body. It was explained that in the Republic of Korea, it is traditionally thought that women who donate their ova are making a ‘sacrifice’ for which compensation should be given. Moreover, as the traditional ‘master-disciple’ relationship is still a strong element in Korean society, professors have great influence on students and young researchers. Nonetheless, it was recalled that the remuneration of gamete donation has been banned in national law since January 2005.

47. Finally, given the wide range of cultures which make up the continent of Asia, together with the absence of an intergovernmental organization for bioethics in Asia, some requested the establishment of a regional intergovernmental framework for discussion and debate on bioethical issues, to enable reflection on common positions.

VII. Conclusions

48. In accordance with Article 2 paragraph (2) of its Statutes, IBC has defined its programme of work. In the light of debates on consent and social and health-care responsibility, and noting the importance of continuing and deepening reflection on these two principles as set out in the Universal Declaration on Bioethics and Human Rights, the Committee decided to set up a working group on each of these subjects. Further to this, in the light of Article 25 of the Declaration, IBC reaffirmed its wish and its members’ availability to assist UNESCO in activities aiming to promote and disseminate the principles of the Declaration at the international, but also regional and national levels.

49. During a reserved meeting, the Committee elected its new Bureau. Before voting by secret ballot, in accordance with its Statutes, the Committee decided not to consider as eligible those members of IBC whose terms of office would expire at the end of 2005 and who had already served two consecutive terms of office (who could not therefore be nominated again by the Director-General in accordance with Article 6 paragraph (3) of the Statutes of IBC, which stipulates that ‘The Director-General shall not appoint the same person for more than two consecutive terms of office’). In addition,
cultural diversity and equitable geographical distribution were taken into account, in accordance with standard UNESCO practice.

50. Membership of the new Bureau is as follows:

- **Chairperson:** Ms Nouzha Guessous Idrissi (Morocco)
- **Vice-Chairpersons:**
  - Mr Leonardo de Castro (Philippines)
  - Mr Gabriel d’Empaire (Venezuela)
  - Mr Eugenijus Gegenius (Lithuania)
  - Mr David Adedayo Ijalaye (Nigeria)
- **Rapporteur:** Mr Claude Huriet (France).

**IX. Closure of the twelfth session of IBC**

51. At the end of the twelfth session of IBC, Ms Michèle S. Jean, outgoing Chairperson of IBC, congratulated the new Chairperson and the other members of the Bureau on their election. She recalled the extremely enriching and constructive debates that had taken place during the three days of the session, in the light of the Universal Declaration on Bioethics and Human Rights. She considered that the Declaration was not an end in itself, but the beginning of a new era of discussion and reflection on bioethics, which would no doubt continue in a spirit of dialogue and mutual respect. At the end of her term of office as Chairperson of IBC, but also as a member of IBC, Ms Jean thanked everyone on the Committee for the experience she had shared as part of it for a number of years, using two tools which were dear to her: scepticism and visionary spirit.

52. Ms Nouzha Guessous-Idrissi, the newly elected Chairperson of IBC, thanked the Committee for the confidence it had shown in electing her to the role of Chairperson and ensured members that IBC would continue to work in the same spirit of conviviality, collegiality and open-mindedness that had prevailed since the Committee was set up. She then announced the Committee’s programme of work for 2006-2007 and concluded by warmly thanking Ms Jean for all that she had brought to the Committee during her term of office and hoping that she would remain actively associated with the work of the Committee.

53. Mr Sané thanked the Japanese Government, Sophia University and the Japanese National Commission for their hospitality and their contribution to the successful organization of this IBC session, the first to be held on the continent of Asia. The wealth of discussion had once again shown how sessions held outside UNESCO’s Paris Headquarters contributed to raising public awareness of bioethical issues in the four corners of the world, as well as strengthening cultural exchange through debate. The ideas which
had been developed during the discussion of a range of subjects in the course of this session would be of great help to UNESCO in carrying out its activities in the field of bioethics, in particular its policy of promoting and disseminating the principles of the Declaration. Mr Sané congratulated the new Bureau on its election and concluded by paying tribute to outgoing members of IBC, in particular Mrs Jean, for their unfailing dedication to the work of the Committee and to upholding the ideals of UNESCO.

54. Mr Tomosuke Kasuya, Professor at the Law Faculty of Sophia University, concluded the twelfth session by thanking UNESCO and IBC, together with all of the participants, for making the session a success.
ANNEX

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Paris, 5 September 2005
Original: English/French

TWELFTH SESSION OF THE
INTERNATIONAL BIOETHICS COMMITTEE OF UNESCO (IBC)
Tokyo, Japan, 15-17 December 2005

Agenda

1. Opening of the Twelfth Session of IBC;
2. UNESCO and Universal Principles in Bioethics: What's Next?
3. UNESCO Declarations in the field of bioethics and cultural diversity;
4. Informed Consent;
5. Social Responsibility: Public Health and Health Care;
6. Contemporary Problems of Bioethics – Asian Perspectives;
7. Election of the Chairperson, four Vice-Chairpersons and the Rappor-
teur*;
8. Proposals for the work programme of IBC for 2006-2007*;
9. Closure of the Twelfth Session of IBC.

* Items 7 and 8 will be dealt with during meetings reserved for the members of IBC.
Chapter 2

**Universal Declaration on Bioethics and Human Rights**

*The General Conference,*

*Conscious* of the unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

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

*Resolving* that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity’s response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment,

*Recalling* the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human

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1. Adopted by acclamation on 19 October 2005 by the 33rd session of the General Conference of UNESCO.
Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,


*Also noting* international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, which was adopted in 1997 and entered into force in 1999, together with its Additional Protocols, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association
on Ethical Principles for Medical Research Involving Human Subjects, adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences, adopted in 1982 and amended in 1993 and 2002, Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law, Recalling the Constitution of UNESCO adopted on 16 November 1945, Considering UNESCO’s role in identifying universal principles based on shared ethical values to guide scientific and technological development and social transformation in order to identify emerging challenges in science and technology taking into account the responsibility of the present generations towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data and taking account not only of the current scientific context but also of future developments, Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals, Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms, Recognizing that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors, Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole, Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, is
the common heritage of humanity, but emphasizing that it may not be
invoked at the expense of human rights and fundamental freedoms,
Also bearing in mind that a person’s identity includes biological, psycho-
logical, social, cultural and spiritual dimensions,
Recognizing that unethical scientific and technological conduct has had a
particular impact on indigenous and local communities,
Convinced that moral sensitivity and ethical reflection should be an integral
part of the process of scientific and technological developments and that
bioethics should play a predominant role in the choices that need to be
made concerning issues arising from such developments,
Considering the desirability of developing new approaches to social respon-
sibility to ensure that progress in science and technology contributes to jus-
tice, equity and to the interest of humanity,
Recognizing that an important way to evaluate social realities and achieve
equity is to pay attention to the position of women,
Stressing the need to reinforce international cooperation in the field of
bioethics, taking into account, in particular, the special needs of developing
countries, indigenous communities and vulnerable populations,
Considering that all human beings, without distinction, should benefit from
the same high ethical standards in medicine and life science research,
Proclaims the principles that follow and adopts the present Declaration.

General Provisions

Article 1 - Scope

1. This Declaration addresses ethical issues related to medicine, life sci-
esences and associated technologies as applied to human beings, taking into
account their social, legal and environmental dimensions.
2. This Declaration is addressed to States. As appropriate and relevant,
it also provides guidance to decisions or practices of individuals, groups,
communities, institutions and corporations, public and private.

Article 2 - Aims

The aims of this Declaration are:
(a) to provide a universal framework of principles and procedures to
guide States in the formulation of their legislation, policies or other
instruments in the field of bioethics;
(b) to guide the actions of individuals, groups, communities, institutions
and corporations, public and private;
(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;
(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;
(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;
(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
(g) to safeguard and promote the interests of the present and future generations;
(h) to safeguard and promote the interests of the present and future generations.

Principles

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

*Article 3 – Human dignity and human rights*

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

*Article 4 – Benefit and harm*

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.
Article 5 – Autonomy
and individual responsibility

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

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual’s informed consent.

Article 7 – Persons without the capacity to consent

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

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effec-
tiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual’s human rights. Refusal of such persons to take part in research should be respected.

**Article 8 – Respect for human vulnerability and personal integrity**

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

**Article 9 – Privacy and confidentiality**

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

**Article 10 – Equality, justice and equity**

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

**Article 11 – Non-discrimination and non-stigmatization**

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

**Article 12 – Respect for cultural diversity and pluralism**

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.
Article 13 – Solidarity and cooperation

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

Article 14 – Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.
2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:
   (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;
   (b) access to adequate nutrition and water;
   (c) improvement of living conditions and the environment;
   (d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;
   (e) reduction of poverty and illiteracy.

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:
   (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
   (b) access to quality health care;
   (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
   (d) support for health services;
   (e) access to scientific and technological knowledge;
   (f) capacity-building facilities for research purposes;
   (g) other forms of benefit consistent with the principles set out in this Declaration.
2. Benefits should not constitute improper inducements to participate in research.
**Article 16 – Protecting future generations**

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

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

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

**APPLICATION OF THE PRINCIPLES**

**Article 18 – Decision-making and addressing bioethical issues**

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

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

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

**Article 19 – Ethics committees**

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

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.
**Article 20 – Risk assessment and management**

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

**Article 21 - Transnational practices**

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.

4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.

5. States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.

**Promotion of the Declaration**

**Article 22 – Role of States**

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.
Article 23 - Bioethics education, training and information

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

2. States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non governmental organizations in this endeavour.

Article 24 – International cooperation

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

2. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 25 – Follow-up action by UNESCO

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

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

*Article 26 – Interrelation and complementarity of the principles*

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

*Article 27 – Limitations on the application of the principles*

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

*Article 28 - Denial of acts contrary to human rights, fundamental freedoms and human dignity*

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.
Chapter 3

SPEECHES AT
THE TWELFTH SESSION OF IBC

- His Imperial Highness the Crown Prince
- Mr Koïchiro Matsuura,
  Director-General of UNESCO
  (opening speech)
- Mrs Michèle S. Jean,
  Chairperson of IBC
  (opening speech)
- Mr Kenji Kosaka,
  Minister of Education, Culture, Sports, Science and Technology of Japan
  (opening speech)
- Mr (Prof.) Yoshiaki Ishizawa
  President of Sophia University, Tokyo, Japan
  (opening speech)
- Mrs Michèle S. Jean,
  Outgoing Chairperson of IBC
  (closing speech)
- Mrs Nouzha Guessous Idrissi,
  Chairperson elect of IBC
  (closing speech)
- Mr Pierre Sané,
  Assistant Director-General for Social and Human Sciences,
  Representative of the Director-General of UNESCO
  (closing speech)
- Mr (Prof.) Tomosuke Kasuya,
  Professor at the Faculty of Law, Sophia University, Tokyo, Japan
  (closing speech)
I. His Imperial Highness the Crown Prince

I am pleased that the twelfth session of the International Bioethics Committee of UNESCO has been convened here in Tokyo with such a large number of esteemed participants and representatives from various countries around the world.

The remarkable progress of science and technology has brought great benefits to humankind, such as highly sophisticated industries and better living standards. It has also provided the means to influence the global environment and the very existence of human beings and other living things.

Life sciences, in particular, have developed in recent years further than we expected. At the same time, it is undeniable that many people wonder whether such developments will be able to find accord with the order of nature.

In order to render science and technology truly beneficial to the welfare and future of humankind, it is crucially important to examine, from an ethical perspective, whether research and development of science and technology are conducted in an appropriate way and whether their achievements are properly utilized. In the light of science and technology now developing on a global scale, it is indispensable to study ethical issues, not only at the level of individual researchers, engineers or nations, but also in the form of international cooperation and collaboration.

This session of the International Bioethics Committee, based upon the adoption of the Universal Declaration on Bioethics and Human Rights at the General Conference of UNESCO this past October, is significant as the first step to make the Declaration concrete. I have great expectations that active discussions in this session will serve as a catalyst for further advances toward development of science and technology harmonized with the dignity of life and the welfare of humankind.
In conclusion, I sincerely hope that the activities of the International Bioethics Committee, gathering wisdom from around the world, will encourage sound development of life sciences and that science and technology will contribute to the future of humankind.
Your Highness,
Mr Minister,
Madam Chairperson of the International Bioethics Committee,
Mr President of Sophia University,
Excellencies,
Ladies and Gentlemen,

I would like to begin by expressing my sincere thanks to the Government of Japan for responding favourably to my desire to hold a session of the International Bioethics Committee (IBC) for the first time in Asia. I am delighted to open this twelfth session of IBC here in Tokyo today.

We are greatly honoured by the presence of His Imperial Highness Crown Prince Naruhito at this opening ceremony. His interest in bioethics in general and the work of IBC in particular is, I am sure, much appreciated by everyone here. Indeed, his presence makes this a most auspicious occasion.

I wish to thank Mr Kosaka, Minister of Education, Culture, Sports, Science and Technology, for being with us this afternoon, and Mr Ishizawa, President of Sophia University, for welcoming us within this important house of learning and reflection.

Since the very beginning of UNESCO’s bioethics programme in 1993, Japan has given its unfailing support. I am aware of the extent to which Japan is involved in international ethical reflection on science and technology. I am very pleased to greet the former Chairperson of IBC, Professor Ida, and I thank him for taking part in this opening session. As a member of IBC, he contributed greatly to the work of the Committee, and later, as chairperson of the Committee from 1998 to 2002, he provided IBC with
vital leadership during a period of transition following the adoption of the Universal Declaration on the Human Genome and Human Rights.

A major component of bioethics is the diversity of ethical views, not only internationally but also within a particular culture. While contributing to the enrichment of the world, cultural diversity is inevitably accompanied by difficulties of apprehension and mutual understanding. This is why UNESCO has decided to organize sessions of IBC on a regular basis outside Headquarters in Paris, thereby facilitating interaction between IBC and the public from different regions of the world.

Geographically, the Asian continent is vast and its cultural range is equally broad. During this session, therefore, it will be interesting to explore the different perspectives of bioethics within the various regions of Asia and to see how, on the same continent, bioethics issues can be addressed in different ways.

Your Highness,
Ladies and Gentlemen,

The Universal Declaration on Bioethics and Human Rights was adopted by acclamation by the Member States of UNESCO at its General Conference in October 2005. This constitutes a major achievement for UNESCO in the field of bioethics. The Declaration is the result of a common effort carried out over two years by IBC, governmental experts and the Secretariat. Civil society, relevant intergovernmental organizations, the scientific community and the general public were also involved in the process through numerous consultations at all levels. Member States themselves, on the occasion of the debate on this issue at the General Conference, expressed their satisfaction with the transparent and participatory process leading to the emergence of a consensual text.

Please allow me here to thank all the members of IBC and in particular its Chairperson, Mme Michèle Jean, for their invaluable work. I am grateful not only for their high expertise but also for their readiness to accept the challenge of bringing their task to successful completion despite the time constraints imposed. In doing so, IBC, a body of independent experts, has fulfilled its role as a neutral ethical advisory body to UNESCO.

On the basis of a preliminary draft declaration elaborated by IBC in February this year, governmental experts met in order to finalize the text. It is fair to say that the final text adopted by Member States in October does not differ greatly in its content from the text elaborated by IBC in February. I am convinced that an international agreement on a subject as sensitive as
bioethics could not be reached without sound preparatory work of genuine intellectual independence - in the case of UNESCO, that is precisely the role of IBC. I know that I can count on IBC to help UNESCO in the dissemination of the Declaration.

Let me now briefly say a few words about the Declaration itself. By drawing on the 1948 Universal Declaration of Human Rights, the new Universal Declaration on Bioethics and Human Rights clearly enshrines the specific domain of bioethics in international human rights law. Under this aegis, it deals with ethical issues raised by medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions. It is thus conceived as a set of general provisions and principles that, first, allow for a better evaluation of the implications of the ethical issues at stake and, second, provide assistance in decision-making in this field. It does not aim to resolve all the bioethical issues presently raised and that evolve from day to day.

By adopting this Declaration, Member States have solemnly affirmed, for the first time in the history of bioethics, the moral commitment of the international community to respect a certain number of universal principles for humanity in the development and application of science and technology, set forth within a single text. In the debate on this issue in October, many States considered this Declaration as a milestone in international standard-setting in bioethics. They stressed that it should be treated integrally with the two other UNESCO Declarations in this field, that is to say, the Universal Declaration on the Human Genome and Human Rights of 1997 and the International Declaration on Human Genetic Data of 2003.

Your Highness,
Ladies and Gentlemen,

The Universal Declaration on Bioethics and Human Rights is at the heart of this twelfth session, which is indeed the occasion for IBC to look ahead and consider the future of the Declaration. On the one hand, ways and means of implementing the Declaration will be explored during the forthcoming days and, on the other, IBC will have the opportunity to reflect further upon three major principles set forth in the Declaration. The principles are as follows.

First, respect for cultural diversity – this is a principle of paramount importance to UNESCO, especially in terms of how cultural diversity can be balanced with universal principles.
Second, informed consent – despite being a well-established principle in medical practice, this is a sensitive and wide-ranging issue that remains open to debate.

And, third, social responsibility in public health and health care. With this particular principle, the Declaration opens up perspectives for action that reach much further than just medical ethics and stresses the need to place bioethics within the context of reflection open to the political and social world.

Clearly, bioethics goes far beyond the code of ethics of various professional practices concerned. The Universal Declaration paves the way for a new agenda of bioethics at the international level and it is incumbent upon IBC to start reflecting on this. Its adoption is just the beginning. To give full life to the Declaration and render it effective, the most important part of the work remains to be done. Concerted action on the part of UNESCO and its Member States should be undertaken, and IBC and the Intergovernmental Bioethics Committee (IGBC) should work hand-in-hand in this endeavour.

In the resolution by which Member States adopted the Declaration, Member States invited me ‘to take the necessary steps to enable IBC and IGBC to contribute appropriately to the implementation of the Declaration and dissemination of the principles set forth therein’, which echoes Article 25 of the Declaration. Thanks to its members, IBC can provide a valuable contribution and, during this twelfth session, the Committee will therefore start reflecting on ways and means to implement the Declaration.

As I stated at the General Conference in October, after an intense period of standard-setting action, the Organization needs to take a normative pause. This is why UNESCO will now focus its action on supporting implementation at regional and national levels, through education and awareness-raising, through the dissemination of the principles set out in the existing UNESCO Declarations in the field of bioethics and, whenever possible, through their integration into national legislation.

Let me mention three major project activities in the bioethics programme that already have been planned towards this end.

The first project is the Global Ethics Observatory (GEObs), which aims at developing a world-wide network of databases in bioethics and other areas of applied ethics such as environmental ethics, science ethics and technology ethics. The GEObs will be officially launched this evening, with three databases on experts, institutions and teaching programmes that will be available free to the public on the Internet.
Secondly, UNESCO will continue its efforts and action in promoting the establishment of national bioethics committees by providing concrete support to those States requesting our assistance.

The third activity is the Ethics Education Programme (EEP), which in fact was initiated last year. It consists of projects focusing on the following: infrastructure for developing and implementing teaching programmes; the development and promotion of ethics programmes; the resources required for implementing ethics programmes; and the creation of a fellowship fund. All these activities will contribute to the dissemination and implementation of the principles set forth in the Declaration.

Your Highness,
Ladies and Gentlemen,

On 16 November this year, UNESCO celebrated its sixtieth anniversary. Widely considered to be the conscience of the United Nations system, in the 1970s UNESCO began to pay heed to the ethical issues raised by science and technology. By virtue of its ‘ethical watch’ mandate, it was in the 1990s - with the creation of IBC - that the Organization developed a programme of bioethics. If UNESCO has become the leading agency in bioethics at the international level, it is largely due to the work carried out by IBC, especially its valuable contribution to international debate and reflection. IBC is indeed an international think-tank of bioethics.

Allow me to conclude by paying tribute to the individuals behind the acronym ‘IBC’ and, in particular, to those members of IBC whose mandate will come to term at the end of this year. Many of them have been involved in IBC’s work since the inception of UNESCO’s bioethics programme in 1993. They have participated in the elaboration of the Universal Declaration on the Human Genome and Human Rights adopted in 1997 and the subsequent two Declarations, as well as in various working groups giving advice on specific subjects such as neurosciences, pre-implantation genetic diagnosis and germ-line intervention, intellectual property and genomics, the use of embryonic stem cells in therapeutic research, and many others.

Over the years, they have offered their expertise and knowledge, their culture, their openness to other cultures, their spirit of dialogue and exchange, their willingness to accept and consider different perspectives and to seek consensus. A certain atmosphere reigns within IBC – it is an ambience that is relaxed and friendly but at the same time serious and of a high intellectual level. To those members whose term of service is ending, particularly to its retiring Chairperson, Mme Jean, I wish to extend my sin-
cere and warm congratulations on a job well done. Thank you very much for helping UNESCO to construct the defences of peace in the minds of men and women.

Thank you.
Mrs Michèle S. Jean,
Chairperson of IBC
(opening speech)

Your Highness,
Mr Director-General,
Excellencies,
Ladies and Gentlemen,

At the invitation of the Japanese Government, we are meeting here in Tokyo for the twelfth session of the International Bioethics Committee of UNESCO (IBC). I would like to express my sincere gratitude to the Japanese Government for its generous offer to host this session. I also would like to express my gratitude to the President of Sophia University for welcoming us.

My last visit to Japan was for a meeting on bioethics in Asia, organized by my friend, Mr Ryuichi Ida. This meeting offered me the opportunity to hear directly from Asian countries about their views on many important bioethical issues: organ transplants, genetic data, civil society participation, conceptual approaches to bioethical issues, etc. This experience, as many others that I benefited from by participating in conferences in Iran, Turkey, Lithuania, Mexico and Argentina, were extremely valuable to me during the drafting of the Universal Declaration on Bioethics and Human Rights.

This session is particularly important. It is the first one since the adoption of the Declaration that called for so much work from IBC. I would like to thank the Director-General who has supported the process with generosity and commitment. Without his support, I do not think that it would have been possible to complete such a complicated endeavour. I would also like to thank the Drafting Group and its Chair, Judge Michael Kirby, and all the members of IBC who participated in the process, not forgetting the continuous support of the Secretariat.
We have tried to put in place a participatory and transparent process to develop the Declaration and this was recognized by the Member States during the General Conference. Again, this process gave an opportunity to all those who are interested in these issues to express themselves, but it also raised the challenge for IBC. As we all know, there are different conceptual approaches to bioethics and we had to choose based on what we heard and what was achievable during the time allotted to us.

We cannot make light of the fact that this was an ambitious undertaking. However, I believe that your full cooperation enabled us to produce a text that, of course, does not meet each and every requirement of all the IBC members and of all the Member States but which, I feel, nevertheless reflects the pragmatic consensus we reached.

The text we produced was examined in April and June at two meetings of governmental experts, in accordance with the ‘rules of the game’ at UNESCO, which is normal since it is the Member States that ultimately approve a text.

I have attended these meetings and they were, if I may say so, very lively, thus showing the importance that Member States attach to the elaboration of a declaration even if it is not a binding text. Although they expressed their views and made some changes to the text, I have to say that the vision that we had in producing the text remains there. The scope, the objectives and the principles are substantially the same. At the request of Member States, the text contains less ‘shall’ and more ‘should’, but from what I heard during the General Conference, there is a willingness in many countries to implement the Declaration by setting up ethics committees, bioethics programmes and mechanisms to engage civil society in the debate. The Declaration is addressed to States, but as it is said in its scope, it ‘... also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private’. So the call to action is clearly spelled out.

Now, we should ask ourselves: how do we follow up? This will be, for a large part, the focus of our discussions during this session: what’s next? Because a text like that will not be worth the paper it is written on if it is not followed by a well prepared implementation plan. I have already made quite a few presentations since the adoption of the Declaration, and I must say, that people, whether they be scientists, members of civil society, academics, medical students, high school students, have shown great interest and posed a lot of questions about the implementation process. The panel and the discussions that we will have will give us some guidance for the future.
In asking the IBC to produce such a declaration, I think that Member States were acting with a visionary spirit. We only need to read and listen to the news to see how important it is for science to have a conscience, how important it is for scientists to act in a responsible manner and how important our principle on social responsibility is. In a large percentage of the planet, populations suffer from a lack of access to health services, and lack of access to food and clean water. Some people are already saying that bioethics should not mingle with these issues and only be concerned with the biomedical issues. But I think that IBC has listened to those who have told us that we should not only be concerned about biotechnology and new fields of research, but also with social issues. And we have done that.

Now, it is time to look to the future, and at being involved in the implementation of the normative instruments that we have produced and that have been adopted by UNESCO on bioethics. What are the best strategies? This is what we will discuss during this session and I am glad that we are doing that here. I am also glad that we have a session on cultural diversity because this is an area that has a very important impact on the decision-making process in bioethics.

During the deliberations of IBC, I must say that all the members acted with a sense of respect for each other and that they listened very carefully to the different views expressed and I would like to thank them for that.

In view of the fact that bioethics deals with human life, it raises very difficult and complex questions on which consensus is not easy but can be reached.

In conclusion, I would like to say that I hope the same spirit of solidarity, serenity and peace will inspire our discussions during this session.
IV. Mr Kenji Kosaka,
Minister of Education, Culture, Sports, Science and Technology of Japan
(opening speech)

Your Imperial Highness,
Mr Matsuura, Director-General of UNESCO,
Madam Chair of the International Bioethics Committee and Distinguished Members of the Committee,
Mr President of Sophia University,
Distinguished Participants,
Ladies and Gentlemen,

It is a privilege to address you in the presence of His Imperial Highness the Crown Prince on behalf of the Ministry of Education, Culture, Sports, Science and Technology, at the opening of this twelfth session of the International Bioethics Committee.

The remarkable development of life sciences and medicine in recent years has not only elucidated various phenomena related to life, it has also greatly contributed to improvements in the prevention of illness, medical examinations, medical treatment and health. On the other hand, such scientific developments have made it possible for humans to tamper with the functions of life, and have given rise to issues touching upon the dignity of life and the fundamentals of human rights.

Research activities in the life and medical sciences now transcend national boundaries and are being carried out through international cooperation and competition on an international scale. In such a context, bioethical issues are not simply a domestic concern for each country. Undertakings based on international cooperation have become essential. Nevertheless, perspectives on bioethical issues vary greatly according to the history, culture and religion of each nation or ethnic group, making it difficult to formulate common international standards and principles. Any reflection on bioethical issues should emphasize the establishment of a common set of global rules based on the dignity of life, while respecting this diversity of views.
Under such circumstances, it is quite significant for such a session of the International Bioethics Committee to be held by UNESCO, as the specialized United Nations agency in the fields of education, science and culture, and for consideration to be given to common principles and their implementation policies on a world-wide scale. Above all, this session of the International Bioethics Committee is being held in the wake of the adoption, during last October’s 33rd session of the General Conference of UNESCO, of the Universal Declaration on Bioethics and Human Rights, the first universal and comprehensive international guiding principles on the subject. I believe that significant discussions will take place here on the principles agreed upon in this Declaration, as well as on policies to apply them in the actual practice of life and medical sciences.

In order to deal appropriately with the issues of bioethics, the Japanese government has been carrying out surveys and examination of important matters related to bioethics through the Council for Science and Technology Policy’s Expert Panel on Bioethics and through the Science Council of Japan’s Special Committee on Life Science and Bioethics: 21st Century Directions. Moreover, we are preparing the necessary legislation and guidelines while reinforcing cooperation between the Ministry of Education, Culture, Sports, Science and Technology, which is in charge of promoting science and technology, and related government agencies.

In order to establish such rules, Japan is of course taking into account an analysis of the situation in other countries. The newly adopted Universal Declaration on Bioethics and Human Rights must serve as the foundation for the examination of bioethics rules in each country, including Japan. I am extremely pleased by the fact that this session of the UNESCO International Bioethics Committee, which comes at such an important time, could be held in Japan.

In order to ensure the establishment of bioethics on an international scale, all concerned bodies including international organizations, national governments, the scientific community, the industry, NGOs and others, will have to join hands towards a common idea and deepen their collaboration. I fully expect that the outcomes of UNESCO’s work in this field will contribute to the sound development of life sciences and medicine, as well as to the welfare of humankind.

Finally, I would like to extend my sincere wishes that this twelfth session of the International Bioethics Committee of UNESCO will result in fruitful and successful exchanges among UNESCO and Member States. I also wish to express my deepest gratitude to our host, Sophia University, and to all those concerned with the organization of this event.
V. Mr Yoshiaki Ishizawa,
President of Sophia University, Tokyo, Japan
(opening speech)

Nothing gives me greater delight than the honour of holding this Twelfth Session of the International Bioethics Committee of UNESCO (IBC) at Sophia University today in the presence of His Imperial Highness Crown Prince Naruhito. I also welcome Mr Koïchiro Matsuura, Director-General of UNESCO, Mr Kenji Kosaka, Minister of Education, Culture, Sports, Science and Technology, and many other distinguished guests and participants in attendance from Japan and from overseas. On behalf of Sophia University, I thank you.

Today’s meeting of IBC is a gathering of medical scientists, bioethicists and experts in various other fields who have whole-heartedly tackled the issues of bioethics — crucial issues facing all of humankind — in every part of the world. Allow me to express my deep respect for your on-going activities and to bid you all a warm welcome.

The rapid development of the life sciences over the last six decades has given rise to myriad issues involving life and our control over life that are indeed crucial issues for all people in all countries of the world.

In October 2005, the General Conference of UNESCO unanimously adopted The Universal Declaration on Bioethics and Human Rights, a momentous document drafted by IBC and deliberated by intergovernmental meetings.

I firmly believe that this Declaration marks a major step for the people of the world, the first step into a new era velle.

Working now with this Universal Declaration on Bioethics and Human Rights as a framework, this meeting will develop discussion from various perspectives. We will begin with further deliberations on issues such as ‘The Universal Declaration and cultural pluralism’, ‘Informed consent’ and ‘Public health and health care.’ As this is the first meeting of the Committee to be held in Asia, we will also be discussing ‘Bioethics and the Asian perspec-
tives’. I expect this meeting to considerably advance our efforts to implement the Declaration.

Throughout our discussions at this meeting, I earnestly hope that the Universal Declaration on Bioethics and Human Rights will become a guiding principle for achieving the bright future envisioned in every country in the world, in every field, and at every social level. Lastly, I hope that by meeting over the next three days, we will forge fruitful and lasting intellectual relationships with each other.

Thank you.
VI. Mrs Michèle S. Jean,
Outgoing Chairperson of IBC
(closing speech)

Mr Sané,
Ladies and Gentlemen,
Dear members of IBC,

Firstly, I would like to congratulate the new Chairperson and the members of the Bureau on their election. I would also like to congratulate them for agreeing to serve bioethics in these strategic posts.

We are now coming to the end of our journey. For many of you, it is the end of a meeting; for me and some other members of the International Bioethics Committee (IBC), it is the end of our formal participation in the Committee. I say formal, because I am sure that all those whose term of office has come to an end will continue to care about the implementation and the dissemination of the three Declarations.

During the last three days we have navigated on sometimes calm and sometimes choppy seas. But bearing in mind the Universal Declaration on Bioethics and Human Rights and being guided by it, we have covered very interesting and challenging topics.

Our first session was entitled ‘UNESCO and universal principles in bioethics: what’s next?’. We heard many good ideas and suggestions during this session and I am unable to mention all of them. Suffice to say that the suggestion made by Dr Ijalaye to try to get the approval of the Declaration by the United Nations is an interesting idea that will, hopefully, be pursued. This first session also saw the launch of the Global Ethics Observatory and I hope that you will consult it and participate in its development.

The second session on cultural diversity offered us the opportunity to discuss how it can be possible to unite, without falling into cultural relativism, the use of the 15 principles in different cultural, historical and geographical contexts. This is an important challenge and I am sure that the Committee
will continue its reflection on that matter. The last session on ‘Contemporary problems of bioethics – Asian perspectives’ gave us concrete examples of the application of the principle on cultural diversity and the conceptual challenges it raises.

The third session on informed consent allowed us to see bioethics dialogue at work. I think that for those of you who are not members of IBC it gave an opportunity to understand how we discuss in IBC and how, by listening to each other, we decide on what could form the basis of a consensus.

The session on ‘Social responsibility: public health and health care’ addressed, as it has been said many times, a new principle in bioethics. We are proud to have included it and the presentations showed the extent of the gap between those who have access to health and those who don’t. How we can put this article into action remains to be seen and will constitute one of the topics that IBC will, I am sure, take on board as a priority.

As we have seen, the Declaration is not an end in itself but the beginning of a new era of thoughtful reflection and discussion. I think that the three key words in this process are respect, dialogue and education at all levels of the school system. Without an ongoing dialogue, it will be impossible to achieve the goals put forward by the Declaration.

The 15 principles are the pillars of the Declaration. They are the light in the tunnel, but as we have seen, to make them work, to use them in interrelation and complementarily requires a careful analysis of each situation. Bioethics is not a hard science and it requires flexibility and discussion. Nobody should think that he or she holds ‘The Truth’ and those who believed themselves to be the possessor of ‘The Truth’ and who have tried to impose their views on others have created havoc in history.

I would like to thank the Japanese Government and the University for their wonderful hospitality. Having the opportunity to meet in this beautiful room has permitted us to discuss with serenity. I would also like to thank all the organizers and the interpreters who have done a wonderful job.

At the end of my mandate, I would like to thank warmly my colleagues of IBC without whom I would never have been able to contribute to the accomplishment of our work. I would specially like to acknowledge the work of Justice Michael Kirby, who as the Chair of the Drafting Group, has contributed with intelligence and energy to the preparation of the text of the Declaration. All my thanks also to the Secretariat that has never failed me. Henk ten Have, Director of the Division of Ethics and Technology, Sabina Colombo, Léonie Treguer and Caroline Munier: thank you very much. Thank you also to Mr Sané and to the Director-General for their ongoing support.
I am a historian and I have to say that this is a good background to do this kind of work. It provides you with a sense of what has been or has not been accomplished in the past and the patience to try to contribute to a better future for humanity. I always say that I have two instruments in my toolbox: scepticism and vision – scepticism to continually question and ask questions about the issues at stake and vision to never lose sight of the objectives that need to be achieved.

Chairing this Committee has been a wonderful experience for me. It is always sad to leave such a group, but I leave being reassured that the new Chair and the new Bureau have all the strength and the intellectual capacity to pursue, with all the members, the work needed to implement the Declaration.

In conclusion, I will read a paragraph from The Teaching of Buddha, a paragraph that fits well with the work that IBC has to do:

*Wisdom is the best guide and faith is the best companion. One must try to escape from the darkness of ignorance and suffering, and seek the light of Enlightenment.*

Thank you for your attention and au revoir.
VII. Mrs Nouzha Guessous Idrissi,
Chairperson elect of IBC
(closing speech)

Ladies and Gentlemen,
Dear Colleagues and Friends,

I should like to begin by saying how pleased I am to be participating in this closing ceremony of the 12th session of IBC, and how sincerely and deeply moved I am following my election as Chairperson of the International Bioethics Committee. This election, which testifies to the confidence of my IBC colleagues, honours me all the more as I thus succeed three outstanding Chairpersons, namely Mrs Lenoir, Mr Ida and Mrs Jean. All three have done remarkable work, and I am sure that all members of IBC have accordingly more than appreciated, under their leadership, their experience as members of the multidisciplinary and notable committee that IBC is. And here I fully endorse what Professor Ida said yesterday when speaking of his experience. I should also like to thank all my colleagues and friends in IBC and its outgoing Bureau for the exemplary way in which the nominating and election process for the new Bureau was carried out, demonstrating a degree of fair play which, as I see it, perfectly reflects the spirit of IBC and its members.

Now that I have received the confidence of my colleagues to chair IBC, I should like to reaffirm to Mrs Jean my thanks and my respect, as conveyed by the ovation in the room after her speech. She has been a remarkable chairperson, a tireless roving ambassador of IBC, doing all that in the manner of a great lady, quietly and determinedly, irrespective of the difficulty of the task or situation. I know it will not be easy to succeed her, but I am confident of the support and backing that will be extended to me by all members of IBC and its Secretariat.

It may be no coincidence that after more than two years of work in drawing up the Universal Declaration on Bioethics and Human Rights,
which has set out bioethical principles and procedures now recognized as universal, but which has also asserted new principles, such as the principle of social responsibility, which holds that equitable access to quality health care, adequate nutrition, water and housing, and so on, which are fundamental human rights, are also raising ethical considerations ... I therefore think it very significant that it should be at this precise moment that the elections designate a Chairperson of IBC from a developing country.

Concerning IBC's programme of work for the next two years, and as Ms Jean has already said, in accordance with its Statutes, IBC will work to implement the Universal Declaration on Bioethics and Human Rights in UNESCO's Member States, and we already have some recommendations by Professor De Castro on the subject. Furthermore, it has been decided following the deliberations of this session to establish two working groups, one on informed consent and the other on the principle of social responsibility and health. This will no doubt require much work before culminating in recommendations that could be useful in various countries and cultural contexts.

I should like to conclude by thanking all members of IBC whose term of office is coming to an end for their valuable contributions. They are remarkable people without whose input we would have been unable to carry out our work so well. Thank you all - you will be sorely missed! But we are aware of your commitment to bioethics and feel sure that we will be able to count on your experience and expertise in the future.

Allow me also to express my sincere gratitude to the Japanese Government for having invited us to hold our 12th session here in Tokyo, and also to Sophia University for its warm welcome and for having enabled us to work in such comfortable and pleasant conditions.

Lastly, although I cannot promise that at the next session of IBC I will be able to switch from French to English as easily as Mrs Jean, I do nevertheless promise to work at improving my English for the future.

Thank you for your attention.
VIII. Mr Pierre Sané,  
Assistant Director-General for Social and Human Sciences 
Representative of the Director-General of UNESCO 
*(closing speech)*

Madam Former Chairperson of the International Bioethics Committee,  
Madam Chairperson of the International Bioethics Committee,  
Mr Kokichi Kasuya,  
Members of IBC,  
Excellencies,  
Ladies and Gentlemen,

At the conclusion of this twelfth session of the International Bioethics Committee of UNESCO, I should like first of all, on behalf of the Director-General of UNESCO, to reiterate our thanks to the Government of Japan for the kind invitation to host this Session. I also wish to express our gratitude to all the people from Sophia University for their hospitality and in particular to Professor Saku Machino, who allowed us to hold the Session in this honourable institute, and to Mr Takayuki Morisaki for his help and support in the organization of this event. The communication and cooperation between the Secretariat and the Japanese National Commission for UNESCO has been outstanding and is evidence of how UNESCO can work effectively at national level. It is always a great pleasure to work under such excellent conditions. I wish also to thank the interpreters without whom we would not have been able to understand each other, as well as the technical team who provided valuable assistance.

This has been the first session of IBC held in Asia and it has been most heartening to see the interest of the Asian intellectual community during this meeting. Given the high level of discussions held over the last few days, it can be seen that IBC sessions held away from Headquarters are very fruitful, both for IBC itself and for the region where the session takes place. These sessions contribute to raising awareness on bioethical issues in the four corners of the world and to fostering debate and exchange among peoples.
Over the past few days, ideas on ways and means of implementing UNESCO Declarations in bioethics have been put forward and this will undoubtedly serve UNESCO in defining its activities in Asia. Indeed, after Latin America and the Caribbean region and Central and Eastern Europe during the last two years, over the next biennium, 2006-2007, Asia will be one of the two priority regions of UNESCO’s bioethics programme, the second being Africa. A good starting point is the GEObs database, the launching of which we celebrated two days ago.

We also had a very interesting and constructive debate and exchange of views on two particular topics addressed in the Universal Declaration on Bioethics and Human Rights: consent and social responsibility and health. As the new Chairperson of IBC, Mrs Guessous-Idrissi already mentioned, the work of IBC over the next two years will focus on these two topics. We have seen during this session that, while consent is a classical issue in bioethics – to which the Universal Declaration devotes two articles – it remains a crucial subject which requires further discussion and reflection, taking into account developments in science and technology and the various cultural traditions in the world. IBC, as an advisory body of UNESCO, will certainly be able to provide useful and valuable input in this respect.

The session dedicated to social responsibility and public health stimulated enthusiastic discussion and raised major issues. Starting from the paradox that social inequity is still increasing despite remarkable economic growth linked to progress in science and technology over the last decades, a number of ethical issues were highlighted which bioethics has to address. As stated in the Universal Declaration on Bioethics and Human Rights, bioethics nowadays should not be constrained to medical ethics but should be part of a reflection open to the political and social world. As it is always useful to go back to origins, let me mention here the words of Mr Van Rensselaer Potter who first used the definition of bioethics in 1971 when he wrote, that bioethics should strive to create a wisdom, to know how to use knowledge for social well-being, based on a realistic knowledge of the biological character of human beings and the biological world. So it is time now to really take care of these issues in the framework of bioethical reflection.

Ladies and Gentlemen,

I would now like to congratulate the new Bureau of IBC: Mrs Nouzha Guessous-Idrissi as Chairperson, as Vice-Chairpersons Mr Leonardo De Castro, Mr Gabriel d’Empaire, Mr Eugenius Gefenas and Mr David Ijalaye, and Mr Claude Huriet as Rapporteur. After the adoption of the Universal Declaration on Bioethics and Human Rights, the work of the IBC Bureau will be just as essential as it was throughout the elaboration process of the
Declaration. I am confident that the newly elected Bureau will provide major support to the work of IBC.

Please allow me now to pay tribute to those IBC members whose mandate comes to term at the end of 2005 and who are not eligible for a renewed mandate: Mr Roberto Andorno (from Argentina) whose reflections on human dignity, consent and many other issues were always welcome; Mr Hans Galjaard (from the Netherlands) who at times when it was necessary, always managed to bring our discussions back to reality, particularly regarding global issues and reproductive health; Mr Mohammad Hamdan (from Jordan) whose sensitivity and trust in UNESCO’s action - in particular in the Universal Declaration on the Human Genome and Human Rights - has been invaluable; Justice Michael Kirby (from Australia) who was at the helm of the Drafting Group and whose competence contributed significantly to the success of the Universal Declaration on Bioethics and Human Rights; Mr Patrick Robinson (from Jamaica) whose vast experience in international law was invaluable particularly in the framework of the elaboration of the International Declaration on Human Genetic Data; and Mr Michel Revel (from Israel) and Mr Hector Gros Espiell (from Uruguay), both founding members of IBC. Over the last 12 years, they have given tirelessly of their time and energy and have contributed enormously to the high quality of the work of the Committee. From the Universal Declaration on the Human Genome and Human Rights in 1997 to the Universal Declaration on Bioethics and Human Rights in 2005, Mr Revel has shared unsparsingly his scientific knowledge in genetics as well as his good common sense; and on more than one occasion, IBC was privileged to have recourse to the wisdom and guidance of Ambassador Gros Espiell. Ambassador Gros Espiell, often referred to in UNESCO as the ‘father’ of the Universal Declaration on the Human Genome and Human Rights, has also been more than generous in helping UNESCO attain its goals in standard-setting action in the field of bioethics.

I now come to the former Chairperson of the Committee, Madame Jean – even in English she has been known to us all as MADAME JEAN. Nominated as a member of IBC in 1998, Madame Jean chaired the Committee from 2002 to 2005. It cannot be denied that she has been masterful in her leadership of the Committee during this particularly intense period of work, ensuring that IBC successfully accomplish its mandate, in particular with regard to the Universal Declaration on Bioethics and Human Rights. Apart from her knowledge and competence, what we will remember from Madame Jean is her open-mindedness, her dynamic spirit, her capacity to engage in dialogue and to listen to others and her personal commit-
ment to the cause of ‘bioethics’. And on a personal note, the members of the Secretariat of UNESCO will have pleasant memories of her kindness and friendship. For all this I say ‘Thank you Madame Jean!’.

Finally, I wish to thank all those who by participating in this session have expressed their interest in the work of UNESCO, particularly to the former Chairperson of IBC, Mr Ryuichi Ida, and I should like to bid farewell to you all and ‘Bon voyage’ to those who are returning to their various countries.

Thank you for your attention.
IX. Mr (Prof.) Tomosuke Kasuya,
Professor at the Faculty of Law, Sophia University,
Tokyo, Japan
(closing speech)

With your permission, I would like to speak in Japanese. My name is Tokosuke Kasuya and I am a Professor here at Sophia University. With the assistance and collaboration of all of you, I am very, how shall I say, relieved, that we have arrived at this closing ceremony.

I would like to introduce the people who have been at the heart of this session and who have worked tirelessly to make it such a success: Prof. Machino of Sophia University who has spent many sleepless nights preparing for this session, Mr Akiyama from the Ministry of Education, Culture, Sports, Science and Technology and the rigorous standard of work of the Japanese civil service, and Ms Kudo from the Secretariat who was faced with a task that was completely foreign to her and she has accomplished it very well.

The organization of this twelfth session of the International Bioethics Committee was an entirely new experience for us. It is all very well to begin something but to achieve something never done before is somewhat more complicated. For the past year we have been preparing for this closing ceremony – in fact you could say for the last 100 years - since this is the very first time that a session of the International Bioethics Committee has been held in Asia. In organizing this session we have learnt much about the Committee and its activities and, our conviction of the good of its work for humankind and for the future has been confirmed.

Sophia is an international university and we had always wanted to host an international conference like this; so it was with much pleasure that we responded to the invitation to welcome the Twelfth Session of IBC.

Furthermore, Sophia University will soon celebrate its centenary and for the first time in our history we have had the privilege of hosting an international conference of this calibre. We are particularly proud to do so in the company of the dignitaries and authorities here with us today.

I thank you all very much for your attendance.
### Composition of IBC in 2004-2005

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<tr>
<th>Name</th>
<th>Term of Office</th>
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<tr>
<td><strong>Andorno Dr (Mr) Roberto Luis</strong> (Argentina)</td>
<td>2002-2005</td>
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<td>Research Fellow at the Centre for Ethics, University of Zurich, Switzerland</td>
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<td>Former Visiting Professor of Bioethics, University of Göttingen, Germany</td>
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<td>Former Professor of Civil Law, University of Buenos Aires</td>
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<td><strong>Berlinguer Prof. (Mr) Giovanni</strong> (Italy)</td>
<td>2004-2007</td>
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<td>Professor of Medicine</td>
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<td>Member of the European Parliament</td>
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<td>Honorary Chairperson of the National Bioethics Committee</td>
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<td>Former Director of the Department of Human and Animal Biology and of the Post-graduate course in Bioethics, University of Rome</td>
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<td><strong>De Castro Prof. (Mr) Leonardo</strong> (Philippines)</td>
<td>2004-2007</td>
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<td>Professor of Philosophy, University of the Philippines</td>
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<td>National Coordinator of the Philippine Bioethics Network</td>
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<td>Secretary of the International Association of Bioethics</td>
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<td>Vice-Chairman of the Forum for Ethics Review Committees in Asia and the Pacific</td>
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<td>Vice-President of the Asian Bioethics Association</td>
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<td>Member of the National Ethics Committee</td>
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<td><strong>Dos Santos Prof. (Mrs) Heloisa Gonçalves</strong> (Portugal)</td>
<td>2002-2005</td>
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<td>Professor of Medical Genetics</td>
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<td>Genetics Consultant to the Directorate of General Health</td>
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<td>Coordinator of the Bioethics Committe of the Portuguese Society of Human Genetics (SPGH)</td>
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<td>Founding Member and Former Chairperson of the SPGH</td>
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<td>Former Chief of the Medical Genetics Service, St Maria University Hospital, Lisbon</td>
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Dow Justice (Mrs) Unity (Botswana) 2004-2007
Judge of the High Court of Botswana
Co-founder of Women and Law in Southern Africa Research Project
Member of International Women’s Rights Watch

D’Empaire Prof. (Mr) Gabriel (Venezuela) 2004-2007
Professor of Bioethics, Central University of Venezuela
Director of Coronary and Intensive Care Unit, Hospital de Clínicas Caracas
Director of the Institutional Review Board for Clinical Investigation,
Bioethics Clinical Association
Guest Member of the National Academy of Medicine of Venezuela

Elungu Prof. (Mr) Alphonse (Democratic Republic of Congo) 2004-2007
Professor of Philosophy, University of Kinshasa
Chairperson of the Congolese Association of Philosophers
Member of the African and Madagascan Council for Higher Education
Consultant to the Agency for Cultural and Technical Cooperation

Evans Prof. (Mr) Donald (New Zealand) 2004-2007
Professor of Philosophy
Director of the Bioethics Centre, University of Otago
Member of the National Ethics Advisory Committee of New Zealand

Galjaard Prof. (Mr) Hans (The Netherlands) 2002-2005
Emeritus Professor of Human Genetics
Former Head of the Department of Clinical Genetics,
University Hospital Rotterdam

Gefenas Prof. (Mr) Eugenijus (Lithuania) 2002-2005
Associate Professor of Biomedical Ethics, University of Vilnius
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Founding member of the Central and Eastern European Association of Bioethics

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Professor of Constitutional Law, Universidad Nacional de Educación a Distancia
Director of the Postgraduate Programme of Constitutional Health Law and of the Postgraduate Programme of Assisted Reproduction
Member of the Experts Committee, Bioethics Institute of the Foundation of Health Sciences
Member of the Bioethics Committee, Universidad Nacional de Educación a Distancia
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Chairperson of the UNESCO Consultative Committee on the Teaching of Human Rights, Culture of Peace, Tolerance and Democracy
Former Minister of Foreign Affairs of Uruguay
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Member of the Higher Council of the Lebanese Press
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Former Minister of Higher Education and Scientific Research
Former Rector of the Arab Open University
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Former Special Adviser to the Minister of Foreign Affairs of Canada to the European Commission
Former Vice-Minister of Health of Canada

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Former Head of the Department of Philosophy of the University of Makerere

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President of the Medical Centre of the University of Pecs
President of the National College of Medical Genetics
Member of the Hungarian Academy of Sciences

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Professor of Cellular Biology
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Chairman of the President’s Council on Bioethics
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Professor of Molecular Genetics, Weizmann Institute of Science
Israel Prize for Medicine (1999)
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REVEL Prof. (Mr) Michel (Israel)
ROBINSON Judge (Mr) Patrick (Jamaica)
SALEH Prof. (Mr) Fawaz (Syrian Arab Republic)
TANDON Prof. (Mr) Prakash Narain (India)
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Chairperson of IBC

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Mr (Prof.) Patricio Ventura-Juncá  
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Chile

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President of the Japanese Association for Bioethics

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Mr (Prof.) Yutaka Hishiyama  
Professor at the Science Council of Japan

Mr (Prof.) Saku Machino  
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Ethics and Human Rights Council for Biomedical Research

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I would like to congratulate the International Bioethics Committee of UNESCO for holding its twelfth session in Asia, and I am extremely honoured to give the keynote lecture. I would like to thank Sophia University for welcoming us to its campus and for hosting such an important international meeting.

I would like to emphasize two points in my lecture. One is how bioethical issues should be addressed or have been addressed in Japan; the other is the third basic plan for how we should promote science and technology development, which we are now preparing in our Council and will start next year. There, for the first time, we would like to address issues of bioethics clearly. Also, for the first time, the importance of social sciences has been introduced thanks in great part to Dr Machino of Sophia University and Dr Ida of Kyoto University, who were members of the Bioethics Committee of our Council.

Organization of Council for Science and Technology Policy (CSTP)

There are some expert panels in CSTP. Japanese S&T policy has its prioritized areas; four priority areas and another four equally important areas, eight areas in all. The four priority areas are life sciences, nanotechnology and materials, information and communications technology, and environmental sciences. The others include energy, social infrastructure, manufacturing technology, very typical of Japan’s prioritization, and the
last being frontiers, including ocean science and space science. An Expert Panel on Promotion Strategy for Prioritized Areas determines the priorities for each year.

The Expert Panel on S&T System Reform discusses budget appropriation, i.e. how the total budget is to be distributed amongst the eight priority areas and how to support young scientists. For example, there is the issue of ethics in life science research, how should the budget be appropriated or distributed ethically. Here we need system reform.

In the actual conduct of research activities, what is important is evaluation, what kind of research failed, what was successful and productive. This is carried out by the Expert Panel on Evaluation. So we determine prioritization, perform system reform, and then perform evaluation. These are three important pillars of how we promote science and technology in Japan.

Apart from this, we have specific subcommittees or subpanels, one of which is the Expert Panel on Bioethics. Another is the Expert Panel on Space Development and Utilization, which deliberates on how Japan should advance in international discussions concerning outer space and its peaceful use. Lastly, since intellectual property is another very important issue, we have an Expert Panel on Management of Intellectual Properties to discuss that particular topic.

Now we are most active with the Expert Panel on Basic Policy. Here we are now discussing the third S&T basic plan, which is to start next year.

Hot issues on bioethics in Japan

Today I will discuss the Expert Panel on Bioethics and what have we done so far. The technology is ready, but there are several subjects that we have to address: for example, how to deal with the generative cell and the embryo, in vitro fertilization, gene therapy, tissue engineering, and preimplantation genetic diagnosis. Technology is ready or at least partly ready, but its ethical status is not yet clear. For example, is it possible for us to intervene on the origin of life? Is it permissible to do that? Can we manipulate life itself? Another issue concerns the moral status of embryos: How should they be protected from an ethical perspective? The issue of the foetus: in Japan there is the Euginic and Maternal Protection Law which permits the artificial termination of pregnancy by abortion.

For humans, we have so-called tissue engineering technologies. In Japan, the opportunity for organ transplantation is very limited and therefore many Japanese seek organ sources outside the country by paying a huge
amount of money. How do we deal with the issue of tissue engineering technology. Another issue is SNPs and gene examination, and how to make use of the information of the human genome obtained by SNPs studies. The issue is an ethical one.

Another issue is animal experimentation and animal welfare: From an animal welfare perspective, we should not allow abuse of animals. With regard to genetically modified plants or genetically-modified organisms, GMOs, or GMO-based food, without a social acceptance, how can we consider this? For example, in Africa, sub-Saharan countries have problems with farming and nutrition. Internationally the need for GMOs that are readily available has been discussed but there is much resistance and a very active public debate going on in Japan against the use of GMOs for food security.

Outline of discussion on bioethical issues

Now what are the topics that we have to address? First, there is the ‘Law Concerning Regulation Relating to Human Cloning Techniques and Other Similar Techniques’ brought into force in 2001. In our Council, particularly in our Expert Panel of Bioethics, we have placed three items under this law. We have three mandates to discuss: one is that we have to revise a guideline on the use of human embryos, specified embryos. We also have to revise a guideline about the use of embryonic stem cells (ES cells). In this, we are working with the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW); the two ministries responsible for bioethics.

The third one, ‘Basic Conceptual Approach Relating to Treatment of Human Embryos’, is the most important. This is a very strongly binding ‘Law Concerning Regulation Relating to Human Cloning Technologies and Other Similar Technologies’. The mandate is given a time limit of three years during which time we have to come up with a draft of the guideline on the treatment of the human embryo, and there have already been 32 meetings on this issue. The final draft was put together and approved and endorsed by CSTP on 23 July 2004.

I should have spoken more about CSTP itself. The Chairman is actually the Prime Minister, and the other members include the Minister of State for Science and Technology Policy, the Minister of Education and Culture, Sports, Science and Technology, the Minister of Finance, the Minister of Economy, Trade and Industry, the Minister of Internal Affairs and Communications, the Chief Cabinet Secretary and also eight experts
including myself. Of the eight members, four are full-time members and the others are part-time members and several experts are working in this organization. As I have mentioned, on 23 July last year, the final report on the use of human embryos was approved.

Before describing the product of our work, I would like to tell you a little about our, particularly about some controversies we met with. We had split our work into pros and cons; for example, the ethical or moral status of the human embryo, whether it should be considered as the origin of human life - it must be carefully treated and respected because of the dignity of human life though it is not a human itself. This agreement was the starting point of the discussion. In principle, human embryos should not be made available for research purposes, but there can be some exceptions. In assisted reproductive technology, there is the use of human embryo. There are pros and cons to the issue as to whether these exceptions should be accepted or not, but, because there was no crucial opinion against, it is possible to make and use human embryos for the sake of basic research in assisted reproductive technology. However, it remains an issue whether it should be made available for research creating somatic cell nuclear transfer (SCNT) ES cells, namely therapeutic cloning ES cells, for example such as in South Korea, and the issue is whether Japan should allow this or not.

In our expert panel discussion those who are against said that this should not be permitted. We had a very animated discussion and then finally I made a proposal. That is, we have to consider public opinion: when scientists or medical scientists establish a cell line of human ES cells only for the purpose of their scientific curiosity, it should not be permitted. However, if there is public consensus for acceptance of this under certain conditions, then they must be clearly stipulated - its safety must be secured, and the scientific evidence of its safety must be made available. For example, in animal cloning, there is some concern about the carcinogenicity issue. Scientists should therefore make careful evaluations of these technologies as to their safety. There should be organization for hearing.

Since female cells are to be used, female donors must be protected. The eggs, oocytes donated by women should not be used as tools for research. This is very important; perhaps we will have to write a new law., but if we do that, we will have to wait for public consensus before drafting it. A basic law on bioethics has a possibility; it should not be excluded. But, it is not yet time for that.

The other kind of discussion we had is that because of its importance, this kind of research must be limited to a certain number of research centers - not everybody can do it. In our report, if all these conditions are complied
with, then it is possible to establish a cell line of SCNT-ES cells. There are those who are against this because of the safety issue, and they said that there should be a moratorium now. I respected this opinion. We are very, very careful. However, basic research should be possible only after all these conditions are prepared. So I agree: there should be a moratorium now. But finally, the newspapers stated that the decision was made by majority vote to allow for therapeutic cloning research, and this was fiercely criticized. I made no further comment on this.

At the MHLW and the MEXT, the drafting of the guidelines has begun and no research project will start before the completion of these guidelines. Because there were pros and cons, and there were arguments on both sides, we have to discuss some issues before starting research in the Expert Panel on Bioethics. First, we have to make a guideline; we have to select limited centres that are allowed to do this, and decide how to protect women, the donors of the embryos. Second, if any research using SCNT-ES cells proposes research project, then it has to be carefully reviewed and screened to see whether that kind of research should be allowed to take place or not. If the scientists are not ready to conduct research under the ethical guidelines then it will not be allowed.

This kind of bioethical discussion is going on in other countries. In the United States, there is no federal government funding for this kind of research but scientists are allowed to do research, whatever they want to do: freedom of research, that is the basic idea. In the United Kingdom, they must follow the clearly stipulated explicit rules. In France, there may be a very strong religious constraints because of the majority Catholic population. Therefore, they are now working on bioethical prerequisites for the life sciences as such.

**New science and technology policy in Japan**

In 1995, the Science and Technology Basic Law was enacted, and the First Basic Plan (1996 to 2000) was written. The Second Basic Plan (2001 to 2005) will end next March.

In the First Basic Plan, the governmental R&D expenditure was discussed, along with the size and scheme of distribution. What was proposed was 17 trillion yen over five years. The next proposal was to make 100,000 post-doctorals and young scientists.

In the Second Basic Plan, at least, Japan should invest the equivalent of 10% of the US budget, in other words, 24 trillion yen. Another one is very difficult to achieve, but this was publicized very widely: Japan aims at
reaching the number of 30 Nobel laureates in 50 years. This was widely publicized.

And then, I would like to walk through the Third Basic Plan. In this plan, putting my experience on the Expert Panel of Bioethics to use, first we have to be accountable in the policymaking of science and technology development from ethical perspectives. This is the backbone of our policy.

Next, we often invest in materials. For example, we can purchase extremely expensive DNA sequencers, because they are necessary for genomic studies but sometimes, although not really needed, 100 or so computers or several more DNA sequencers may be purchased because some of the budget remains. We often generously spend money for materials but instead of investing in materials, we should invest more in human resources, and that was the buzzword we created: ‘materials to humans’.

It sounds very natural that this is how it should be but it is difficult to achieve. Invest in human resources. Scientists who invest in materials say they need large accelerators to launch large rockets and equipment for Antarctic observations. We exchanged debates about the fundamental budget being investments in human resources, though we could provide the necessary materials. Although we emphasized the importance of investment in human resources, many people were against this, because many scientists were heavily dependent on accelerated technologies, and were a little concerned about the possibility of losing their budget. This is not the point; we would like to give priority first of all to the investment in human resources.

As for university centres for research activities in Japan, Sophia University or Kyoto University are among them, and most of the basic research activities are going on in universities. Universities would like to have more autonomy in terms of deciding how they should spend research funds. These are what we call fundamental investment or fundamental capital; in other words, the money spent for faculty members’ research expenses, book expenses, and they are basic capital.

In the United States, the National Science Foundation (NSF) and the National Institutes of Health (NIH) have competitive research funding on an individual scientist’s proposal basis. For the first time, the combination between them can be now decided by CSTP. Universities were not in favour of this because they thought that the basic budget would be curtailed in order to increase the competitive individual’s research fund resources. But that is not the point: the point is if competitive funding is necessary, it will be considered together with the basic budget under the Third Basic Plan.
As for the universities, their hierarchical structure is a prominent feature. Successful elite universities are at the top of this pyramid. Elitism governs the structure of universities and these elite universities should develop into the true elite universities on a global scale. On the other hand, local universities should work with local public organization, not the scientific fund, in order to improve, for example, the human resources that can contribute to local communities.

In the Meiji era in Japan, there was a reform of the school system, and we have introduced the vocational colleges, public high schools, and the Grand Ecole and others in order to improve the educational level of the public in general. As a result, the good performers are always aiming at studying in universities in large cities like Tokyo, Kyoto and Osaka, and they will never go back to and contribute to their local communities. The hollowing out of human resource at local communities occurs and this is an issue that we wanted to address with this new scheme of research fund allocation.

There is another issue I would like to discuss very briefly. That is the safety and security issue. Science and technology must contribute to the enhancement of public safety and security; for example, we must combat against infectious diseases such as the avian flu and SARS. This is one important emphasis we could put in the This Basic Plan which is still ongoing. It will start for five years from next year. We should be proud of a new beginning of the science and technology policy of Japan.
SESSION I
“UNESCO AND UNIVERSAL PRINCIPLES IN BIOETHICS: WHAT’S NEXT?”

- Mr (Prof.) Ryuichi Ida (Japan)
- Mrs Michèle S. Jean (Canada)
- Mr (Juge) Michael Kirby (Australia)
- Mr (Prof.) David Adedayo Ijalaye (Nigeria)
- Mr (Prof.) Hector Gros Espiell (Uruguay)
- Mr (Dr) Mohammad Hamdan (Jordan)
**Déclaration Universelle sur la Bioéthique et son suivi - Diversité dans l’universalité**

Conférence Magistrale

**M. (Prof.) Ryuichi Ida,**
Professeur à la Faculté de droit,
Université de Kyoto (Japon)

**Introduction**

« Les guerres prenant naissance dans l’esprit des hommes, c’est dans l’esprit des hommes que doivent être élevées les défenses de la paix. » Telle a été l’idée fondatrice de l’UNESCO en 1945. L’UNESCO se consacre à édifier la forteresse pour la paix et la valeur de l’homme. Aujourd’hui, la bioéthique fait partie de cette forteresse pour la défense de la dignité humaine et des droits de l’homme. L’ennemi de cette forteresse bioéthique n’est certes pas la science et la technologie, mais la négligence de la valeur humaine qui est parfois mise en jeu dans le développement des sciences et de la technologie dans ce domaine. La Déclaration universelle sur la bioéthique et les droits de l’homme, adoptée à l’unanimité en octobre dernier par la Conférence générale de l’UNESCO, est une pierre angulaire de cette forteresse. J’aimerais avant tout féliciter le Comité international de bioéthique qui a merveilleusement accompli la tâche éminemment difficile de rédaction d’un instrument normatif d’une première importance. Mes félicitations vont particulièrement au Juge Michel Kirby pour la présidence du Comité de rédaction.

L’idée de la nécessité d’un instrument universel sur la bioéthique en général a été exprimée par plusieurs pays, surtout des pays en développement, lors de la Table ronde des Ministres de la science dans le cadre de la Conférence générale de l’UNESCO en 2001.

Les progrès des sciences de la vie ouvrent la porte vers le bien-être et la prospérité mais, en contrepartie, soulèvent également des questions éthiques, juridiques et sociales qui mettent en jeu des valeurs fondamen-
tales, telle que la vie de l’être humain ou la dignité humaine. C’est la raison pour laquelle la réflexion bioéthique est indispensable face à ce développement des sciences de la vie et que dans chaque pays le débat bioéthique est en cours. Cependant, puisque la nécessité de débat bioéthique est une apparition toute récente, et aussi puisque la rapidité de ces avancements scientifiques et technologiques est incomparablement grande, un nombre considérable de pays ne sont pas tout à fait prêts à résoudre cette problématique et surtout à établir les normes nationales de la bioéthique. Ils ont besoin d’un modèle ou d’une ligne directrice des principes et des normes éthiques applicables à leurs propres pays.

C’est précisément dans cette circonstance que plusieurs ministres des sciences ont exprimé le souhait que l’UNESCO prenne l’initiative de montrer quels seraient les concepts ou principes fondamentaux de la bioéthique. Toutefois, le travail de réflexion et rédaction à cette fin a aussi offert la possibilité de réexaminer l’universalité des normes bioéthiques soi-disant établies. Car ce dont nous parlons est la bioéthique universelle commune à toute l’humanité et à tous les individus, quoi que nous admettions que le mouvement bioéthique soit né dans les pays occidentaux.

Dans tout le processus de rédaction, qui a été entamé sous ma présidence, le Comité international de bioéthique a gardé le sens de l’universalité en affirmant les principes bioéthiques déjà bien ancrés dans différents pays et ceux qui pourraient guider les pays en développement dans le respect de leur propre système de valeurs et traditions culturelles, religieuses et sociales. L’UNESCO, et à tout le moins le CIB, a réussi à combiner ces deux préoccupations en un seul et précieux instrument qui est devant nous.

Avant de passer à la première partie de mon exposé, je voudrais attirer votre attention sur le titre de la Déclaration. L’adjectif « universelle » a une valeur symbolique. Lors de la rédaction de la Déclaration sur le génome humain et les droits de l’homme, il a été question de choisir comme titre « Déclaration universelle » ou « Déclaration internationale ». La conclusion en a été d’entendre que le terme « universel » signifiait l’application des principes énoncés dans la Déclaration de 1997 à toute l’humanité et à chaque individu qu’il soit scientifique, patient ou autre. Une telle interprétation a déjà été donnée il y a soixante ans lors de la rédaction de la Déclaration universelle des droits de l’homme aux Nations Unies, où le Professeur René Cassin a expliqué ce que signifiait « universel ». Cet état d’esprit est de même reflété dans la présente Déclaration. Tant et si bien que les principes énoncés de l’article 3 à l’article 17 s’adressent aux individus, scientifiques, patients et familles ainsi qu’aux participants aux
recherches. Il va de soi que l’ultime responsabilité des questions bioéthiques tombe entre les mains de l’État et que cette Déclaration vise donc au premier plan les États et les décideurs.

_Section I : Mise en place des principes généraux de bioéthique dans la Déclaration_

_Portée de la Déclaration_

Puisque la notion et les normes de bioéthique se basent sur le système de valeur de l’être humain et de son existence dans chaque État et dans chaque communauté, un instrument de bioéthique universel doit avoir à la fois l’universalité des valeurs humaines comme source d’inspiration et la diversité culturelle et sociale en tant que siège des normes éthiques. La nouvelle déclaration de l’UNESCO a réussi la difficile tâche de combiner ces deux éléments souvent antinomiques. L’accent est ainsi mis sur l’universalité de la portée mais en tenant compte de la diversité culturelle.

Il y a un choix à faire entre deux directions lorsqu’une déclaration sur la bioéthique universelle doit être formulée. La première est d’établir les normes concrètes pour l’ensemble des pays dans le monde, et surtout pour les pays qui ne sont pas encore suffisamment armés d’instruments nationaux de bioéthique, qu’ils soient contraignants ou non. Si l’on suit cette direction, l’on devrait préparer des dispositions concrètes et claires sur chaque grand sujet de bioéthique, tels que la greffe d’organes, la génomique, les cellules souches embryonnaires, le clonage, l’euthanasie, etc. La deuxième direction est de se limiter à affirmer ou clarifier les principes généraux de bioéthique qui reflètent les concepts et les valeurs de base communs à toute l’humanité. Les États peuvent se baser sur ces principes dans leurs discussions sur chaque question de bioéthique afin d’établir la législation ou les réglementations nationales. Dans ce cas, les principes et les normes directeurs sur chaque question n’apparaîtraient pas clairement dans le texte de la Déclaration.

Le CIB et l’UNESCO ont apparemment suivi cette seconde option. Il en résulte que la Déclaration doit être considérée comme une déclaration de cadre institutionnel pour le débat bioéthique au niveau national et non véritablement une déclaration de normes précises de la bioéthique. Il va de soi que dans une prochaine étape, l’UNESCO et le CIB devraient traiter chacune des questions dont les normes ne sont pas disposées encore
dans la Déclaration. Cela veut dire que le CIB a pris une approche en deux étapes.

Il en résulte que la Déclaration est de la nature des instruments de principes qui servent comme cadre fondamental universel et n’entrent pas trop dans le détail. Une telle mesure permettrait aux États de discuter en leur sein les normes éthiques applicables à chacun des contextes nationaux de recherche ou de pratique médicale ou de la compréhension des populations sur les avancements des sciences et technologies de la vie. Nous félicitons les efforts du CIB de montrer ainsi les principes fondamentaux de bioéthique dans cette Déclaration.

**Le cadre général**

La Déclaration se compose de deux grandes parties, c’est-à-dire celle des principes de la bioéthique universelle et celle de la mise en œuvre. Une telle structure elle-même montre la double tâche de combiner les deux éléments mentionnés ci-dessus.

La Déclaration est une déclaration de principes, qui permettent aux États et aux décideurs en tant que responsables de la bioéthique de réfléchir et de discuter chaque question éthique en suivant leur propre système de valeur dans la décision de bioéthique. Ainsi, les principes énumérés de l’article 13 à l’article 17 sont les noyaux durs de l’universalité, tandis que la partie concernant la mise en œuvre commençant par l’article 18 prévoit les mesures d’application des principes à suivre par l’État et sert comme garantie de la diversité.

**Principes généraux de la bioéthique**

Le cadre général étant ainsi dit, 15 principes énumérés sont véritablement les noyaux durs de la bioéthique universelle. Il est vrai que, comme indiqué dans l’article 26, ces principes sont interdépendants et complémentaires entre eux. Ces principes sont aussi complémentaires au niveau national, puisqu’ils seront appliqués selon le système de valeur de chaque communauté et chaque État. Ainsi, ces principes fonctionnent à la fois comme point de départ de la compréhension et de la promotion de la bioéthique et comme point d’aboutissement de la discussion et de la résolution des questions éthiques, juridiques et sociales.

La section sur les principes a une double vision : l’une, protection de chaque personne humaine concernée dans la médecine et dans la science et les technologies, et l’autre, adaptation du phénomène à la mondialisation. Le principe de la dignité humaine ainsi que celui du consentement éclairé, se situent dans la première instance, tandis que la diversité culturelle et la
solidarité et la coopération internationale, dans la seconde. Il est exactement la raison d’être de l’UNESCO, maison des sciences et de la morale pour tous, de mettre cette double vision en marche.

Un autre aspect ne doit pas être négligé. Parmi ces 15 principes, nous trouvons un signe de la montée de l’« Humanité » sur le podium en tant que sujet principal des normes bioéthiques. Les concepts tels que la dignité humaine, la protection des générations futures, l’environnement et la biodiversité sont des concepts qui concernent avant tout l’Humanité dans son ensemble.

En fait, l’Humanité est déjà apparue sur la scène dans le domaine juridique international au fur et à mesure que le développement de la science et de la technologie s’est avancé. Nous avons par exemple le concept du patrimoine de l’humanité, concept particulièrement cher à l’UNESCO, la mission de l’humanité dans l’espace ou encore l’assistance humanitaire dans les hypothèses émergées aujourd’hui. La naissance de Dolly et le débat sur le clonage chez l’être humain nous ont certainement fait remarquer l’importance suprême de la notion d’humanité. D’ailleurs, le concept de la dignité humaine joue le rôle principal dans l’interdiction du clonage humain reproductif, et a ainsi un lien étroit avec cette tendance à la valorisation de l’Humanité.

Section II. Application des principes

Application des principes dans la diversité de contexte

Cependant, la généralité des principes ne garantirait pas la compréhension et la mise en œuvre des conceptions incluses dans ces principes. Nous ne devrions pas nous contenter d’énumérer ces principes. Ces concepts ont souvent des connotations propres à la civilisation et aux pensées occidentales. L’application des principes à chaque instance nécessitera la clarification sur ce que signifie chacun de ces principes dans le contexte national et culturel.

Prenons quelques exemples. Les relations entre l’autonomie et la valeur commune d’une communauté donnée peuvent être différentes selon les civilisations ou les modes de vie. L’inséparabilité du corps et de l’esprit est une notion importante propre à certaines communautés, dont le Japon, où la transplantation d’organe du cadavre se trouve en difficulté. L’idée du sacrifice volontaire pour les intérêts d’autrui pourrait servir d’appui pour l’avancement d’approvisionnement d’organes à greffer ou de matériaux humains pour la recherche ou les traitements médicaux. La notion
d’incarnation et la valeur de la divinité sont aussi deux exemples ayant un impact fort d’un point de vue religieux ou culturel, dont il n’est plus place ici de développer.

Parmi d’autres, le concept de la dignité humaine, jouant le rôle principal dans la bioéthique, n’est pas aisément définissable. Il peut être dépendant du système de valeurs de chaque communauté.

Le cas du Japon est certes significatif en ce sens. La question du clonage humain a été longuement et profondément discutée au sein de son Comité national de la bioéthique dans le processus de la préparation de la loi de 2000 relative à l’application de la technique de clonage chez l’homme, par laquelle le clonage humain reproductif est interdit, le clonage dit thérapeutique étant laissé à la réglementation éventuelle du Ministère de l’Education. Selon le Comité japonais, comme dans d’autres pays, le clonage humain reproductif n’est pas aisément dénissable. Il peut être dépendant du système de valeurs de chaque communauté. Cependant, il nous a fallu préciser le contenu exact de la dignité humaine, sans quoi la reproduction d’être humain par la technique de clonage ne saurait être un acte punissable du point de vue criminel. Le Comité japonais a conclu qu’il y avait trois éléments dans la notion de dignité humaine dans le cas de la reproduction humaine par le clonage.

La reproduction d’un être humain par la technique de clonage nous amène à l’instrumentalisation de l’être humain pour un objectif particulier tel que la greffe d’organe.

La prédétermination de la combinaison génétique et ainsi des particularités génétiques de la personne humaine clonée est une violation grave de l’individualité et de l’identité, dont le respect est clairement prévu comme fondement de droit et de la liberté fondamentale de l’homme dans la Constitution du Japon.

Le clonage reproductif est une reproduction asexuelle sans fertilisation par les deux sexes. Cela va au-delà de la conception fondamentale de la naissance d’une vie humaine dans la société japonaise et, partant de là, cela causerait un désordre social et surtout la destruction de l’ordre familial.

L’accumulation de ces trois éléments définit la dignité humaine, quoique de manière négative.

D’autres exemples peuvent être cités sans entrer dans le détail, tel que le consentement ou le partage des bienfaits. Dans les pays asiatiques, souvent la valeur de la famille, unité de base des relations humaines, est soulignée, non pas pour nier la valeur de l’individu ou de l’individualisme mais afin de valoriser le lien humain à un haut niveau. Les bienfaits, dans la
même ligne de considération, ne sont pas toujours définissables et dépendent de la situation sociale du pays en cause.

Il n'y a aucune intention ici de dire que la définition de la dignité humaine donnée par le Comité japonais de la bioéthique ne soit différente de celle en Occident ou soit propre à la nation japonaise. Non plus pour le consentement ou les bienfaits. Mais, tout simplement, ce sont des exemples qui montrent la difficulté d’appliquer les normes de valeur universelle dans un contexte de diversité culturelle et sociale.

**Mise en œuvre des principes de la Déclaration**

La partie relative à l’application et au suivi, intitulée « Application des principes » et « Promotion de la Déclaration », c’est-à-dire, de l’article 18 à l’article 25, visent l’institutionnalisation des réflexions et des décisions bioéthiques.

La Déclaration présente les normes universelles de bioéthique sur la base desquelles chaque État ou chaque communauté ou encore chaque institution devrait organiser un débat, afin d’établir les codes éthiques applicables dans chaque instance appropriée, suivant leurs propres systèmes de valeurs concernant la vie humaine, tant dans l’organe législatif que dans l’administration nationale ou locale, tant au comité national de bioéthique qu’aux comités locaux, tant dans les institutions de recherche ou dans les hôpitaux que dans les entreprises médico-pharmaceutiques, ou encore tant dans les médias que dans l’éducation à la bioéthique, ou même dans la famille.

La Déclaration demande donc aux États, en tant qu’entité de responsabilité ultime concernant la bioéthique, de faire tous leurs efforts afin de comprendre le fond des principes généraux énoncés dans la Déclaration et de mettre en évidence des principes dérivés adaptés à leur contexte culturel, social, juridique, éthique et économique. La Déclaration elle-même ne pourrait être un instrument d’application directe dans le domaine de la recherche ou des traitements médicaux. La responsabilité de l’application devrait être conférée à tous ceux qui sont concernés dans la recherche et ses applications à chaque niveau.

Les normes bioéthiques ne sont pas forcément sous forme de droit ou d’instrument législatif. Elles pourraient être soit sous forme législative, soit sous forme de directives ou de règles ministérielles contraignantes ou non-contraintes, soit sous forme d’auto-régulation professionnelle, ou bien sous toute autre forme possible si la communauté donnée en décide ainsi. C’est exactement ici l’État et son peuple qui prennent la décision sur
la question de savoir sous quelle forme les instruments nationaux devraient être établis.

Il a été question, dans le processus de rédaction, de prévoir le suivi systématique par des rapports nationaux réguliers soumis à l’examen du Comité international de bioéthique. Il est vrai que la Déclaration entre dans la série des instruments pour la protection des droits de l’homme, dans lesquels le système de rapports nationaux a une fonction efficace de mise en œuvre. Cependant, la bioéthique universelle ne me semble pas encore arrivée au même stade de développement et de compréhension que celui des droits de l’homme dans le sens strict du terme. L’application effective des normes bioéthiques dépend, surtout et avant tout, de la compréhension et de la réflexion sincère sur la valeur de la vie humaine de la part des personnes concernées et aussi par le public dans son ensemble. La conscience de la bioéthique ne vient pas du haut mais se génère dans la vie de tous les jours.


J’en arrive à mon dernier mot en guise de conclusion. La Déclaration universelle sur la bioéthique et les droits de l’homme n’est pas une fin en soi. Elle est un point de départ ou un levier vers l’universalisation efficace adaptée dans notre monde de diversité. Les principes énoncés dans la Déclaration sont bien établis dans beaucoup de pays. Mais ils ne sont en quelque sorte que des embryons qui seront élevés dans l’utérus de la Terre par la nourriture de la compréhension, de la prise de conscience et de la mise en valeur dans chaque communauté humaine. Ainsi, nous passerons un jour très proche le pont au « pays de la bioéthique », si j’ose me référer à un livre du Professeur Giovanni Berlinguer, ami et membre du Comité. Nous avons devant nous un chemin éclairé par la Déclaration. Il n’y a pas un seul chemin. Tous les chemins mènent, non pas à Rome, mais à la Maison de la sagesse qui est l’UNESCO. Le Comité international de bioéthique a encore d’énormes tâches à accomplir. Mais il le mérite. Guidez-nous, chers amis du Comité, car l’avenir de la valeur de l’homme dépend de vous.
On 19 October 2005 the General Conference, at its 33rd session in Paris, adopted the Universal Declaration on Bioethics and Human Rights. The communiqué issued by UNESCO states: ‘The text, adopted by acclamation, addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions’. The text adopted today provides a coherent framework of principles and procedures that can guide Member States in the development of national policies, legislation and codes of ethics. Wherever such an ethical framework is lacking, the Declaration will incite and assist in filling the gap. While it is still up to States to create legal texts and instruments appropriate to their cultures and tradition, the general framework proposed by the Declaration can help globalize ethics in the face of the increasingly globalized sciences.

Now that the Declaration has been adopted after two years of intensive work, it is time to ask ourselves: what’s next?

UNESCO with the help of IBC has now produced three Declarations in the field of bioethics: The Universal Declaration on the Human Genome and Human Rights (1997), the International Declaration on Human Genetic Data (2003) and the Universal Declaration on Bioethics and Human Rights (2005).

I will talk about three points:
1. the implementation of the Declaration;
2. topics that could form part of the IBC future program of work;
3. the process leading to the production of a declaration and at the same time the role of IBC, IGBC and the government experts.

1. **The implementation of the Declaration**

I would like here to refer to an example taken from my experience working with governments on the development and on the implementation of many policies. I have to say that in the policy-making process, the steps that lead to the adoption of a policy receive a lot of attention and energy from ministers. The implementation of that same policy does not raise the same level of preoccupation. And after some time has passed, a minister would ask: ‘What is happening with this policy? Have we succeeded in implementing it properly?’.

Generally speaking, from my viewpoint, the implementation is as difficult and challenging as the development. The proliferation of information that we live with renders this process very difficult. This is why I think that the Director-General, reflecting the views of Member States, rightly said at the end of the General Conference in October:

> En même temps je partage le sentiment exprimé par de nombreux intervenants qui considèrent avec raison que nous avons atteint la fin d'un cycle et qu'il est désormais temps de porter notre attention vers la mise en œuvre des instruments existants, notamment par des actions d'éducation, de sensibilisation et de renforcement des capacités.\(^{(1)}\)

As we know, ‘Even the best ideas result in failure if poorly executed. Implementing ideas and programs requires having a clear understanding of the individuals and organizations involved; the tools to achieve your goals; and clear, specific, desired outcomes’\(^{(2)}\). Those are goals that are not easy to achieve in an organization like UNESCO with such a variety of cultures and socio-economic background.

Based on its experience and understanding the challenge, IBC had suggested in its text many articles that can be related to the implementation of the Declaration. Some of these articles were modified by the government experts, but I must say that the spirit in which they were drafted by IBC has been retained.

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For example, Article 1 clearly states that the Declaration is addressed to States. It also says that it will provide guidance to ‘decisions or practices of individuals, groups, communities, institutions and corporations, public and private’. So, right at the beginning of the text, there is a will to involve all the actors that can play a role in the application of this Declaration.

There are also articles that put forward important ideas about the way to implement this Declaration; I will mention a few knowing that my colleagues on this panel will go into more details on that matter:

**Article 19** on the setting up of ethics committees independent, multi-disciplinary and pluralist, one of their task being to foster debate, education, public awareness of, and engagement, in bioethics.

**Article 20** on risk assessment and management.

**Article 21** on transnational practices, which provides guidance on how to avoid exploitation of countries that contribute to research projects by stating, inter alia: ‘...transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized’. Also: ‘when negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation’.

**Article 22** that calls for States to: ‘take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information’.

We have said many times that this Declaration is not an end in itself but the start of a process. To put that into action, IBC had, in Article 28 of its project, suggested many concrete actions that UNESCO could do to follow-up, like reaffirming its commitment to deal with ethical aspects of the biosphere, and to elaborate guidelines and international instruments as appropriate on ethical principles related to the environment and other living organisms. Also, IBC was asking for a revision of the Declaration if needed by the development of science and technology. Although Member States have chosen to be less specific, there is still in **Article 25** a strong call for UNESCO to promote and disseminate the principles set out in the Declaration and to deal with bioethical issues with the help of IBC and IGBC.

I think that there are projects already started that will help in the implementation like the rotating conferences, the data bank of experts and the project on creating a databank on legislations that are or will be created.
2. **Topics that could form part of the IBC future programme of work**

Although the implementation of the three Declarations will be the major component of the IBC future programme of work, a couple of other issues could be tackled.

The Declaration has stated principles that are well known in the field of bioethics, but has also added principles that are new in that kind of document. A few examples: **Article 5** on Autonomy is labelled ‘Autonomy and Individual Responsibility’ and reads: ‘the autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected...’ So it is not autonomy wall to wall, but autonomy with responsibility and attention to others. In the same vein and at a time where health systems are facing very difficult resource allocation dilemmas, the relationship between individual and collective benefits could be studied.

**Article 14** on social responsibility and health is a very important article. I have had the chance to take part in some of the rotating conferences held in Iran, Turkey, Lithuania Argentina and Mexico. Many participants told us that we had to pay attention to the fact that, even though research was offering new exciting possibilities, many countries do not have access to proper food, water, health care and public health and they asked us to reflect that in the Declaration. This principle is the result of this request and I hope that it will be seen as an integral part of human rights.

How can this principle be implemented? How can IBC contribute to this task? These questions have to be answered and IBC could work on that.

Other topics that could be pursued:

**Consent:** I think that the time has come to reflect on consent. There are a lot of issues around its application in population data banking, conservation of data, epidemiological studies, the type of consent that should be used, understanding of consent forms, etc.

**Respect for cultural diversity and pluralism:** I believe IBC should study the application and meaning of the principles in different cultural contexts. At the invitation of Professor Ida, I took part in a conference on bioethics in Asia and I learnt a lot about the different perspectives that can lead to the application of a principle.

Many specific issues related to the beginning and the ends of life were suggested to us as issues that could be dealt with in the Declaration. They are very important topics. We have chosen to keep the Declaration at the level of a framework that could be used in working on other issues. But, in
the coming few years, these other specific issues could be included in the IBC programme of work.

3. The process leading to the production of a declaration and at the same time the role of IBC, IGBC and government experts

These three Declarations have been produced through processes that have followed different paths.

When the first declaration was produced IGBC had not yet been created. During meetings that led to the adoption of the first declaration, governments asked to be better informed during the making of such a text and this led to the creation of IGBC.

In the making of the Universal Declaration on Human Genetic Data, IGBC was involved through meetings with IBC. During the government experts meeting it became evident that the collaboration between IBC and IGBC could be more substantial to provide better information to government experts when they meet and to receive suggestions from IGBC.

The production of the Universal Declaration on Bioethics and Human Rights was done through extensive consultations with Member States (two written consultations) and with all the stakeholders (extraordinary sessions, all the versions put on the web). This transparent process was recognized by many States during the General Conference. In January 2005, with the Chair of the drafting group, I participated in the IGBC meeting to explain our text. Following that, IGBC and IBC had a joint meeting where the discussion was frank and open. IBC then studied all the proposed amendments and decided to retain some of them and to reject others, which is its prerogative. The government experts then had two meetings (April and June) to look at the text.

Even though I think that this time the process was ameliorated, there is still room for improvement.

IBC spends a lot of time thinking, discussing and writing its texts. So I think that it should always have the opportunity to explain its view to IGBC and to government experts when they meet. When this has been done, it has, I think, been very productive. Saying that, I understand that, at the end of the day, Member States are the one who will adopt or reject a text, but this should be done having a full understanding of what is behind the wording of IBC. So, this is something that still needs to be looked at by both by IBC and by IGBC.

Finally, during the making of the Declaration we had the opportunity to meet twice with the UN Interagency Committee on Bioethics. The sugges-
tions of the agencies were very useful. This Committee could also, in the future, contribute to the implementation of the Declaration and the work that has been started on intellectual property should be pursued through different mechanisms: conference, papers, etc.

So, as you see the future, is at our door and there is a lot of work to be pursued to give life to the three Declarations. We hope to hear from you during this session about your vision of the future.
UNESCO AND UNIVERSAL PRINCIPLES IN BIOETHICS: WHAT’S NEXT?

Mr (Justice) Michael Kirby,
Justice of the High Court of Australia,
Member of IBC

Where we are

1. A new Universal Declaration: The General Conference of UNESCO on 19 October 2005 adopted the Universal Declaration on Bioethics and Human Rights(1) (“the Declaration”). At the Twelfth Ordinary Session of the International Bioethics Committee (IBC) convened in Tokyo, Japan, 15-17 December 2005, IBC addressed the future programme of UNESCO and of IBC concerned with the universal principles of bioethics. This paper is a contribution to that consideration.

2. In order to discuss ‘What’s next?’ it is necessary to understand where IBC now finds itself. If we know where we have come from and where we are, we will have a better chance of predicting, with accuracy, where we should be going.

3. The completion, effectively in less than two years, of a text for a universal declaration on subjects so important and controversial as bioethics and human rights is, by any account, a significant achievement(2). Under the

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2. The process occurred in three phases. First the IBC formulated a preliminary draft by January 2005 after consultations both nationally and internationally. There were two meetings of the United Nations Interagency Committee on Bioethics (24-25 June 2004, 10 December 2004). There followed a session of the Intergovernmental Bioethics Committee (IGBC) (24-25 January 2005) and a joint session of the IBC and IGBC (26-27 January 2005). Next, the final draft was adopted, after two meetings and several amendments, by the Intergovernmental Meeting of Experts of Member States in June 2005. Finally, the draft was submitted to the General Conference of UNESCO in October 2005.
leadership of the Chairperson of IBC (Mrs Michèle S. Jean, Canada) and the devoted and energetic contributions of the Drafting Group - together, ultimately, with the participation of all members of the IBC - a draft was prepared which formed the basis of inter-governmental consultations. These consultations produced the final text transmitted by the Director-General (Mr Koichiro Matsura) to the General Conference. I had the privilege of serving as Chairperson of the drafting Group. I therefore observed closely the evolution of the text to the point of its final adoption.

4. Alteration of the IBC text: When the Universal Declaration on the Human Genome and Human Rights was adopted by the General Conference of UNESCO on 11 November 1997, the text was almost entirely derived from the document recommended by IBC. The variations that were introduced before that draft of the Declaration was submitted to the General Conference of UNESCO, were few in number. The Declaration was adopted unanimously.

5. By way of contrast, the draft declaration, with the proposed title ‘Universal Declaration on Bioethics and Human Rights’ became the subject of intensive consideration by the Intergovernmental Bioethics Committee (IGBC), a review by invited experts and intensive debate in the two sessions of a governmental meeting of experts aimed at finalizing the draft Declaration. The second such meeting took place from 20 to 24 June 2005. It resulted in a ‘final report’ by its Rapporteur, reviewing the details of the consideration of the IBC draft, the amendments agreed by the governmental meeting of experts and appending a revised text, described as a ‘consensus document’, which was transmitted to the Director-General\(^3\). It is this revised text that was submitted to the General Conference and adopted.

6. A comparison of the draft declaration completed by IBC and the final text approved by the governmental experts indicates two things:
   – the overall structure and contents of the Declaration was unmistakably similar to the document prepared by IBC; but
   – the revised draft contained many changes of concept, content and order, such that the final text was a significant variation of the text submitted by IBC.

7. It is not the purpose of this paper to provide a close textual comparison between the IBC draft and the governmental experts’ draft. No doubt that

\(^3\) SHS/EST/05/CONF.204/6.
comparison will be performed elsewhere. It is sufficient to notice that the main lines of the variations between the two drafts were as follows:

1) minor alterations to the Preamble;
2) deletion of the definition clause (former Art. 1). Most significantly, this included a definition of ‘decision or practice’, a phrase referred to throughout the IBC draft;
3) alterations to the expression, content and order of the principles recommended by IBC. Most especially, the principles in the final draft are expressed at a higher level of abstraction either in the passive voice or with the use of the verb ‘should’. The principles stated in the IBC draft were intentionally expressed with greater particularity, addressed to application to ‘any decision or practice’ involving bioethics and the principles were stated in the mandatory term ‘shall’;
4) most of the substance of the principles has found its way into the Declaration, as adopted. However, in it, an added ‘principle’ appears (Art. 7) on ‘Persons without the capacity to consent’. This was a matter of detail which the IBC draft had preferred to leave within the principle on consent (former Art. 10). It was treated as part of the ‘ethical and legal standards adopted by States consistent with the principles set out in this Declaration’. For ethical reasons, the IBC draft had insisted on ‘ongoing participation of [the] person’ in the provision of consent for medical diagnosis and treatment (former Art. 10). IBC considered that the giving of consent was an interactive process in which the subject took an active and not merely a reactive role. The final Declaration (Art. 6) deletes this notion, which has been an important advance in ethical thinking that was supported by IBC. It replaces the recommendation dealing with persons who do not have the capacity to consent in the IBC draft (former Art. 10(c)) by an entirely new principle, separate from that of consent (new Art. 7) and expressed in some detail;
5) the list of procedural ‘principles’ included in the IBC draft (especially Arts 16, 17, 18 and 19) have been significantly reduced, reordered and re-expressed. An innovation in the IBC draft, dealing with practical rules for bioethical decision-making (former Art. 16) and observance of basic requirements of honesty and integrity, transparency and periodic review (former Arts 17, 18 and 19) was radically abbreviated in the Declaration, as adopted;
6) moreover the IBC draft provision (former Art. 22) on risk assessment, management and prevention was considerably diluted. The draft article approved by the government experts kept risk assessment in
the title (Article 20). However, the actual text is abbreviated to two lines and replaces special attention to instances of ‘serious or irreversible damage to public health or human welfare’ with general expressions, such as ‘appropriate’ and ‘adequate’;

7) IBC proposed machinery for monitoring and evaluating the implementation of the Declaration through IBC and IGBC (former Art. 27(a)). This was replaced by a duty on UNESCO to ‘promote and disseminate the principles’ of the Declaration (Art. 25). This appears to run counter to the demand of many Member States of UNESCO for a pause in normative development but new emphasis on implementation; and

8) the recommended title of IBC for the document (‘Universal Declaration on Bioethics and Human Rights’) was been adopted in place of the former language (‘Universal Norms on Bioethics’) as contained in the IBC mandate.

8. It is necessary to refer to these alterations, which influenced the text submitted to the General Conference of UNESCO. There was no intermediate opportunity of consultation with, or comment by, IBC. As will appear, one issue presented by the foregoing developments concerns the appropriate inter-relationship between an expert advisory body, such as IBC, and Member States of UNESCO, advised by a governmental meeting of experts such as occurred in the preparation of the Declaration.

9. The Declaration’s achievement: Some variations by the governmental experts to the IBC draft represented improvements. Thus, the addition of a new Article (Art. 8) in the Declaration, adding a Principle of ‘respect for human vulnerability and personal integrity’ (which was not, as such, contained within the IBC draft) arguably constituted an improvement in the basic text. Similarly, the addition of a specific new article (Art. 16) on ‘protecting future generations’ (former Art. 3(vii) ‘including [the impact of life sciences] on their genetic constitution’) was arguably an improvement. This issue had been discussed by IBC. It had been dealt with in the IBC draft by including the concept not as a separate principle but as one of the aims of the Declaration [safeguards to be observed throughout the text] (viz ‘to safeguard and promote the interests of present and future generations’). The new Article 8 of the Declaration gives particular and express recognition to the fact that, in applying and advancing scientific knowledge, medical practice and associated technologies, human beings are more vulnerable than they were earlier to harm and to loss of basic rights. This principle does not need to be one reflecting an anti-scientific or anti-technological bias. Many instances, such as the sale of thalidomide for treatment of depression
but causative of birth defects in pregnant women, indicate the heightened vulnerability of human beings in the present age.

10. Other alterations to the IBC draft represented high political policy, upon which the representatives of Member States of UNESCO must necessarily have the last word. Whilst some members of IBC, and bioethicists, may regret the substitution of the passive voice and more vague and general language for the expression of the principles of the earlier draft - as well as the order adopted in the principles and the treatment of the issue of persons without capacity to consent as a principle separate (Art. 7) from the principle of consent (Art. 6) - most of the ideas presented by IBC have survived, in one form or another, in the present text(4).

11. Despite the foregoing changes, several very important advances contained in the IBC draft were preserved in their essential concepts, although they may have been regarded as sensitive and controversial. These included:

1) Preservation of an article concerned with social responsibility. Although, as now appearing, this has deleted (amongst the particular considerations) access to care and medicine including reproductive health, it still includes reference to the ‘health of women and children’. It persists with the IBC’s linkage between bioethical decisions and social responsibility. This is an important advance in basic concepts.

2) Similarly, the innovative inclusion in the IBC draft of former Article 15 (Responsibility towards the Biosphere) is preserved, in its essence, in the new Article 17 (Protection of the Environment, the Biosphere and Biodiversity). This was also sensitive and controversial in some circles. The preservation of this article in the Declaration as adopted was a further important advance in concepts.

4. Thus former Art. 4 (Human Dignity and Human Rights) becomes new Art. 3; former Art. 5 (Equality, Justice and Equity) becomes new Art. 10; former Art. 6 (Benefit and Harm) becomes new Art. 4; former Art. 7 (Respect for Cultural Diversity and Pluralism) becomes new Art. 12; former Art. 8 (Non-Discrimination and Non-Stigmatization) becomes new Art. 11; former Art. 9 (Autonomy and Individual Responsibility) becomes new Art. 5; former Art. 10 (Informed Consent) becomes new Art. 6; former Art. 10(c) (Consent) becomes new Art. 7; former Art. 11 (Privacy and Confidentiality) becomes new Art.9; former Art. 12 (Solidarity and Cooperation) becomes new Art.13; former Art. 13 (Social Responsibility) becomes new Art. 14 (Social Responsibility and Health); former Art. 14 (Sharing of Benefits) becomes new Art. 15; former Art.15 (Responsibility Towards the Biosphere) becomes new Art. 17 (Protection of the Environment, the Biosphere and Biodiversity); former Conditions for Implementation (Arts 16, 17, 18 and 19) to the extent that they are reflected at all, are telescoped into new Art. 18 (Decision-making and Addressing Bioethical Issues).
12. Most especially, the present text preserves the insistence of IBC upon the need for a close relationship between bioethics and human rights.

13. Bioethics can trace its history to ancient times in all major civilisations. Thus, in Europe, it can be traced at least to the Hippocratic Oath in Ancient Greece. The modern history of human rights dates principally from the late eighteenth century. In the United Nations, it has advanced greatly since the Universal Declaration of Human Rights of 1948(5). The revised text of the Declaration preserves this integration of two hitherto largely separate streams of ethical and legal principle. This is the most important achievement of the text. It retains the essential thrust of the IBC draft. In so far as the new Universal Declaration helps to bring together, into an harmonious dialogue, ethicists trained in universal norms of human rights and those trained in the tradition of bioethics, the Declaration, as adopted, will perform a most significant function. It will advance a most important objective of IBC and UNESCO. It will retain most of the essential concepts of the IBC draft. It will ensure that, henceforth, bioethical and human rights analysis will be more closely integrated. This will be the most significant achievement of the Declaration. It is an achievement for IBC. Realising this, attention to ‘What’s Next?’ necessarily addresses first what can be done to translate this achievement into practical reality.

14. **Outline of this paper:** From the foregoing examination of where we have come from and where we are now, this paper will review three topics to answer the question ‘What’s Next?’.

1) First, it is necessary for IBC to address the immediate follow up to the adoption of the Declaration, so as to translate the text, and the ideas that it incorporates, into living reality;

2) Secondly, it is desirable to reflect upon the experience of the governmental consideration of the IBC text (and the many amendments adopted) for the lessons they carry for the future work of IBC and the relationship between the expert and governmental bodies of UNESCO dealing with bioethical concerns; and

3) Thirdly, it is desirable to consider whether, in the long-term, the text of the Universal Declaration on Bioethics and Human Rights might become a foundation for a treaty dealing with that subject.

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Follow-up to the Declaration

15. United Nations and UNESCO: The Secretary-General of the United Nations has indicated a keen interest in the international issues presented by biotechnology. It would be desirable for his staff to be alerted to the adoption of the Declaration so that references to it can be incorporated in his speeches and observations. This is a true United Nations achievement on a cutting edge issue. Without the United Nations, it is unlikely that such a project would be tackled by many governments at all.

16. It may readily be expected that the Director-General of UNESCO, who has given strong support to the work of IBC on the Declaration, will promote knowledge about it and attention to its terms. It is an important achievement of his service as Director-General. Some of the promotional activities below will make more demands on the IBC Secretariat. The staffing and financial implications of following up the Declaration should be drawn to the attention of the UNESCO administration. The adoption of the Declaration is not the end of the project. It is simply the beginning of a new phase. Promotion and implementation demands resources. One of the criticisms of United Nations agencies is the apparent belief of some that the completion of a document is the significant achievement. Of itself, that achievement is limited. The Secretariat should now throw itself into an energetic promotion of the Declaration inside and beyond the United Nations system. The members of IBC, and past members who should be more involved in the IBC network, should assume the responsibility of persuading UNESCO to devote adequate resources to the IBC Secretariat so that it can help IBC to fulfil its mission.

17. The highly successful International Symposium of UNESCO on Ethics, Intellectual Property and Genomics, held in Paris 30 January - 1 February 2001, is a model that should be followed for an early meeting to consider the new Declaration and to attract attention to its terms. Planning for such a symposium should begin at once. It would be desirable to call together participants from IBC, from experts on human rights and experts on bioethics. The future inter-relationship of bioethics and human rights, as envisaged in the Declaration, should be the primary focus of attention. Consideration might be given to satellite symposia. The conduct of one in the United States (perhaps sponsored by the President’s Commission now to be headed by Dr Pellegrino, USA, member of IBC) would be suitable. Symposia in a number of developing countries should also be planned. A UNESCO sponsored conference is to take place in New Zealand in February 2006 which I shall attend.
18. Other agencies of the United Nations should be informed of the Declaration, as doubtless they would be in due course. The attention of units within UNESCO, with relevant responsibilities should be enlivened, including in the Man in the Biosphere Project and the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST). Agencies of the United Nations, having specific interests relevant to the Declaration, should be informed and involved in future symposia. These include WHO, UNAIDS, WTO, WIPO, FAO, UNICEF and the Office of the High Commissioner for Human Rights (OHCHR). UNESCO is the lead agency in these concerns and should exercise its leadership by promoting the Declaration.

19. An idea that might be worth exploring would be a joint IBC/COMEST conference involving Nobel Laureates who, it might be hoped, would endorse the basic principles contained in the Declaration.

20. Transnational agencies: Several transnational governmental agencies have an interest in the terms of the Declaration. These include the OECD (Paris), the Commonwealth Secretariat (London) and the organisations associated with the Francophone States and the Commonwealth of Independent States.

21. International organizations of the academies of sciences, of universities and research agencies should be alerted to the adoption of the Declaration. It would be desirable to have these bodies as observers in future symposia organised by IBC.

22. National governments: It would be highly desirable for national governments to be involved in promotion of the principles in the Declaration. In the past, the G8 leaders have included questions of genomics, access to healthcare and intellectual property on their agenda. There are a number of provisions of the Declaration (most especially the principles on social responsibility and health (Art. 14) and protection of the environment, the biosphere and biodiversity (Art. 17)) that should be called to the attention of such leading world statesmen.

23. It should be an obligation of members of IBC to brief their own governments on the adoption of the Declaration, its provisions and the obligations addressed to Member States of UNESCO. Although IBC Members serve in an independent capacity, their knowledge and experience with the development of the Declaration put them in a favourable position to promote awareness of the Declaration and of its principal provisions.

24. Bioethics bodies: It would be desirable to enlist national and international agencies concerned with bioethics to alert them to the Declaration and involve them in promoting its principles. The International Organisation
of Bioethics Commissions, the Ethics Committee of the Human Genome Organisation and particular institutions with a global outreach (eg the Hasting Center in the United States) should be alerted to the Declaration. It would be desirable for a brief (two page) summary of the principal objectives and provisions of the Declaration to be prepared to assist in the promotion.

25. **Consulting institutions:** It would also be desirable for the IBC Secretariat to consult with specialist bodies within universities, institutes of health, technological institutions and with notable personalities, in order to procure awareness of the Declaration and, if possible, support for its principles.

26. **Concrete illustrations:** Experience teaches that the foregoing could best be done by affording concrete examples of the way in which the Declaration might assist in the resolution of particular problems. One advantage of the IBC’s draft was its specific focus on ‘decisions and practices’ having bioethical implications. The Declaration, as adopted, is expressed in more general language although reference is made in the introduction of the principles to the fact that ‘within the scope of this Declaration, in decisions and practices taken or carried out by those to whom it is addressed, the following principles are to be respected’.

Nevertheless, it would be desirable for IBC to commission a paper preparing case studies to illustrate the way in which, in resolving specific bioethical questions, the Declaration could be put to practical use. Examples and illustrations tend to speak more loudly than generalities, especially general statements expressed in the passive voice. This is particularly true when speaking to scientists, technologists and business leaders. Such elaborations and illustrations could clarify the question of the ‘duty bearers’ under the several principles of the Declaration. Elucidation of that concept, which is multi-faceted, was a frequent observation about the IBC draft and it applies with equal or greater force to the Declaration as adopted.

27. **Business and industry:** It would be highly desirable for the IBC Secretariat to inform major pharmaceutical corporations and businesses concerned in healthcare developments about the Declaration. At a future stage, a special meeting should be convened addressed to the promotion of the Declaration in business and industry. The international organisations involved in manufacturing in the health sector should be alerted to the Declaration and invited to bring its terms to the notice of their members. Translating general provisions, such as appear in the Declaration, into practical decisions at the research bench, company board room and
university committee is a major challenge. However, IBC should rise to it.

28. *Explanatory texts:* An explanatory memorandum was prepared by IBC, based on its own text\(^6\). Although this was not endorsed by the governmental experts it is desirable that a descriptive document be prepared, based on the revised text as adopted in the Declaration, explaining the derivation of the text language, the meaning of the words used and illustrating the ways in which the principles might be translated into practice. The inclusion of illustrations and examples is imperative in such a text, if it is to be useful. Likewise, the inclusion of endorsements and explanations of the text development would be desirable.

29. The IBC Secretariat should give priority to the preparation of such an explanatory document. Moreover, academic scholars in the field of bioethics and human rights should be encouraged to write explanatory texts based on the Declaration, as adopted. If funds are available, the IBC Secretariat should commission the preparation of such a text.

30. *Recording the history:* It would be desirable for the history of the preparation of the Declaration to be recorded both in written form and also in an electronic record. The key players within IBC, IGBC and the governmental experts should be invited to provide descriptive essays of their impressions and recollections of the preparation of the text so that these are available for a future time when a full history is written. The IBC Secretariat should make available to legitimate researchers the records describing the development of the text. Film and sound archives concerning the text should be committed to secure formats. Filmed recordings were taken during some of the closing discussion of IBC and IGBC. The Secretariat should give consideration to commissioning a film documentary on the evolution of the Declaration. Promoting awareness of the Declaration and its most important terms involves explanation of its evolution and of the considerations that inform the principles adopted in the Declaration.

31. It would be desirable for film records of the foregoing to be available to schools, universities, research institutes and individual researchers. The Secretariat should explore how this might be done, within and outside UNESCO.

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\(^6\) The governmental meeting of experts did not agree to the Explanatory Memorandum prepared by IBC. To an extent, this was inevitable as the draft document was addressed to the IBC draft which, in important respects, was superseded. The governmental experts also rejected the IBC proposal for monitoring of Member State compliance with the Declaration by IBC and IGBC (former Articles 27(a) and (b), and 28(c)).
32. **Simplification of Principles**: The Declaration, as finally adopted by the General Conference is, in parts, opaque in its expression. There is a need for greater accessibility to the basic principles. The Secretariat should consider preparing a simplified statement of the core principles, expressed in simple and explanatory language which researchers, ethics committees and individual scientists and technologists could readily understand. Of course, any such simplification would have to be consistent with the text. Preparation of an ‘ethical check-list’, consistent with the Declaration, could be a helpful way to promote its provisions. Alternatively, the core principles, as stated in the Declaration, might be isolated and given widespread publicity. The ordinary scientist and technologist will not be greatly interested in the Preamble or provisions of the Declaration addressed to Member States of UNESCO. But they will be vitally interested in a check-list of bioethical principles which lie at the heart of the Declaration.

33. **Particular sub-topics**: Several of the articles of the Declaration deserve ongoing expert consultation specific to their terms. Thus, future consultations should be convened on bioethics and:

1. Respect for Human Vulnerability and Personal Integrity (Art. 8);
2. Cultural Diversity and Pluralism (Art. 12);
3. Social Responsibility and Health (Art. 14);
4. Protecting Future Generations (Art. 16); and
5. Protection of the Environment, the Biosphere and Biodiversity (Art. 17).

Such consultations should be convened with appropriate experts as each of these principles is novel and requires elucidation and elaboration. One of the objects of the Declaration is consciousness raising. This might be attempted by addressing meetings to the innovative provisions of the Declaration, in particular. The foregoing represent the most innovative of the provisions in the Declaration as adopted.

34. In addition to particular attention to the articles of the Declaration, it is desirable that IBC should not overlook its ongoing work in relation to intellectual property issues and bioethics. This subject can now be advanced with the support of the text of the Declaration. The relevance of the Declaration to the debates over the TRIPS Agreement of the WTO needs to be explored and clarified. The adoption of the Declaration could signal a new momentum within IBC and UNESCO towards addressing the serious bioethical concerns arising from aspects of the TRIPS Agreement. The Vulnerability Principle (Art. 8), the Justice and Equity Principle (Art. 10); the Non-Discrimination and Non-Stigmatisation Principle (Art. 11); the Solidarity and Cooperation Principle (Art. 13) and, especially, the new Social Responsibility and Health
Principle (Art. 14) combine to afford UNESCO new tools with which to tackle the bioethical problems presented by TRIPS. IBC should revive its group working on bioethics and intellectual property. Specifically, the relevance of the Declaration to that debate should be elucidated and drawn to the notice of WTO, WHO, UNAIDS, OHCHR and other relevant bodies.

35. A number of particular topics take on a new relevance in the context of the Declaration. Some of these are to be discussed at the twelfth ordinary session of IBC (eg informed consent; social responsibility; and internationality). In the future, given the adoption in quick succession of three UNESCO Declarations of universal application in the field of bioethics, it may be expected that nuanced attention to particular regional, ethnic, religious and cultural norms will secure more attention.

36. This notwithstanding, there are undoubtedly international issues of bioethics that deserve specific attention by IBC, with fresh stimulus from the new Universal Declaration. These topics include:

1. Issues of intellectual property;
2. The risks of transgenesis;
3. The bioethics of poverty;
4. Feminist perspectives of bioethics;
5. Animal experiments and respect for animal life;
6. Global climate change and bioethics;
7. Bioethical issues for outer-space; and
8. The general principles of ethics in science.

37. It will be important to test responses in each of the foregoing fields against the general principles stated in the Declaration.

**Institutional review**

38. A significant change: The much greater role demanded by governmental experts, affecting in a very significant way the final shape and text of the Declaration, presents issues relevant to the future operations of IBC that need to be considered both by IBC and, more generally, by UNESCO and the Director-General.

39. The entitlement of Member States to have the last say upon the language of a universal declaration, adopted by an agency of States, is beyond question. This is the way the adoption of the principles of the international community achieves a means of accountability to the people of the United Nations who, under the Charter, are the ultimate foundation for contemporary international law.

40. Nevertheless, there are, potentially, aspects of the procedures followed in the adoption of the present Declaration that may need considera-
tion and reflection. This is said, with full recognition of the heroic efforts of the IBC Secretariat and, indeed, of all who took part in the preparation of the Declaration including the governmental experts:

1. The time allocated to the preparation of the Declaration was, in retrospect, somewhat too optimistic given the novelty, complexity and disputability of the issues;
2. The time for governmental consideration, both domestically and at UNESCO, was severely curtailed because of the Organization’s timetable, fixed by the timing of the General Conference;
3. Several of the issues raised in IGBC could be explained by members of IBC, having regard to the procedures adopted and the opportunities for joint sessions at which IBC and IGBC members entered into formal and informal dialogue with each other. The like opportunities for dialogue were severely curtailed in the procedures of the governmental meeting of experts. This is not a criticism of that meeting, which had to conform to its own a severe timetable. However, it explains why it was not always possible for IBC to elucidate for the governmental representatives the reasons for choosing the IBC’s recommended text; the order of the principles that was chosen; and the preference for language that was criticised on various grounds;
4. There remain some difficulties perceived in the language preferred by the governmental experts. The approach to the principle of consent is a case in point. Talk of informed consent, whilst still relevant, should not today be seen as a top-down and one-off process. It should be viewed as a participatory one. That was the reason for part of the IBC text now deleted. It is not clear that this point of bioethical detail was fully appreciated by the governmental experts;
5. The foregoing suggests that an improved procedure is required, in any future activities involving IBC and governmental experts, so that recommendations and difficulties are fully communicated, understood and taken into account before final texts are settled;
6. In some cases, it might have been expected that improved procedures for dialogue and true consultation could have disposed of several problems. In the end, dialogue must conclude with a decision. IBC necessarily must respect the decisions of Member States. However, some concern has been expressed that the governmental experts were not always aware of the reasoning and discussions within IBC. This may suggest the need for a further step in any future consultations of such a kind. If the IBC experts views are not fully available to exchange views with the governmental experts, the result
may be needless or undesirable changes to texts that improved facilities for consultation could obviate or minimise.

41. The IBC Statutes: The experience derived from the consideration of the draft Declaration prepared by IBC in this instance may suggest the need to revisit the terms of the IBC Statutes. In particular, it may desirable necessary to consider improved arrangements for consultations during such procedures with IGBC and intergovernmental experts or representatives, so that a last minute rush is avoided involving governmental experts working under great pressure and without adequate final input and explanations from IBC itself.

42. Self-evidently, the very large numbers of changes made to the text of the IBC draft declaration in the present case, seem to indicate that an improvement of institutional arrangements is desirable. IBC in the first instance, and the UNESCO Secretariat thereafter, should give thought to the improvement of the procedures so that the utility and highest quality of the expert and governmental advice of the IBC to UNESCO can be assured.

43. These observations are put forward in a positive spirit, so that both IBC and UNESCO can learn from the institutional experience derived from the preparation of the Declaration. Some points of difference between IBC and the governmental experts were clear-cut. Such differences of view can be understood and accepted, even where not necessarily agreed (eg substitution of ‘should’ for ‘shall’ in the principles and deletion of ‘decision or practice’ as the working mechanism of the draft declaration). Other changes to the language, order and content of the principles (and especially deletion of the innovative demand for more detail on bioethical practices (former Arts 16, 17, 18 and 19)), together with the insertion of a new ‘principle’ on ‘persons without the capacity to consent’ (Art. 7) (conceptually a subtopic of Art. 6, Consent) leave a feeling that better elucidation of the IBC reasons for (and defence of) its text would have diminished the number, variety, particularity and contestability of the amendments demanded by the governmental meeting of experts. At the least, these are developments that require constructive attention within UNESCO, so as to learn from the recent experience in the preparation of the Declaration.

Further evolution of the Declaration

44. Treaty development?: It is not uncommon for important Declarations of basic principles to give rise, with the passage of time and after further international consultation, to the preparation of treaties aimed to convert the principles of the Declaration into norms of binding international law. This
was the process by which the broad principles of the Universal Declaration of Human Rights of 1948 were ultimately converted into the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights. In due course, the development of treaties of this kind in the field of bioethics will almost certainly occur. Were this not to happen, the long-run risks presented by biotechnology, unregulated by effective international law, are those that are identified in the principles contained in the Declaration - infringement of basic human rights; neglect of the balance of benefit and harm for humanity; failure to develop biological science with proper respect for human vulnerability; and for the other principles referred to in the present Declaration, including the novel principles of social responsibility and health (Art. 14); Attention to the protection of future generations (Art. 16); and protection of the environment, the biosphere and biodiversity (Art. 17).

45. Even if consideration of a universal treaty on bioethics may be seen as premature, there is nothing to prevent regional organisations or groups of countries moving to secure regional treaties, elaborating the Declaration. For example, the Latin American States, which have demonstrated a keen interest in the Declaration, might decide to begin work on a Latin American Convention on Bioethics.

46. A long-term project: It is premature to consider the initiation of a dialogue towards a treaty based on the Universal Declaration of Bioethics and Human Rights. However, the IBC Secretariat should initiate internal consideration of this topic as a long-term project. Any criticisms and problems presented by the present text should be collected and recorded. The full record of commentary on the text should be preserved. The observations of scientists, technologists, manufacturers, bioethical experts, moral philosophers and others should be recorded. In due course, this material will be important for the consideration of any future work towards a treaty which UNESCO may eventually sponsor.

47. Although in their field of competence IBC and UNESCO have, so far, proceeded by way of a series of Universal Declarations, it is possible that a future treaty might draw on a number of the Declarations and contain provisions borrowed from several of them. It could be useful, at an appropriate time in the future, for IBC to convene an international meeting, with appropriate experts, including in international law, to consider those aspects of the Declarations adopted by UNESCO on the recommendation of IBC that might lend themselves to inclusion in a future comprehensive treaty on biotechnology, the biosphere and future generations.
48. No one should be in doubt (and no member of IBC is) of the importance of the work performed on the issues of bioethics, biotechnology and human rights. Truly, these issues concern the future of the human species. Can there be any more important issues for human beings to reflect upon and to ensure that developments conform to the shared principles of human ethics?

49. Members of IBC themselves have a special duty to support UNESCO and the Secretariat. They should promote knowledge about the Declaration, emphasising its innovative provisions and in particular the link that it establishes between bioethics and human rights discourse. Members of IBC also have a duty to consider further issues and to assist IBC to maintain its place as an intellectual leader in the field of bioethics and a significant actor in the global community.
1. Introduction

The second session of the Intergovernmental Meeting of Experts was held at the UNESCO Headquarters from 20 to 24 June, 2005 with the aim of finalizing a draft declaration of the universal norms on bioethics. At the end of this meeting, a final report was produced on 27 July 2005 which I consider to be excellent. I therefore seize this opportunity to congratulate UNESCO and the International Bioethics Committee (IBC) for a job well done. The crucial question posed in this regard is UNESCO and universal principles in bioethics and human rights – what’s next? My answer is simple and laconic. The next step is implementation.

2. Implementation

In my considered opinion, these laudable principles can be implemented in two ways:

(a) *The First Way Out* – The implementation can be carried out in a way similar to that employed with respect to the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO in February 1997. Attached to this Declaration was a document entitled ‘Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights’.

Similar guidelines can therefore be prepared and attached to the Universal Declaration on Bioethics and Human Rights to be endorsed by the General Conference of UNESCO.
(b)  **The Second Way Out** – The second way out, which to me is preferable, is to ask UNESCO to persuade the Secretary-General of the United Nations to request the UN General Assembly to proclaim these laudable principles for the following reasons:

(i) In my humble opinion, the Universal Declaration on Bioethics and Human Rights is so crucial to human existence that it ought to be proclaimed by the United Nations so as to give it a higher status similar if not identical to the Universal Declaration of Human Rights (UDHR) proclaimed by the General Assembly of the United Nations on 10 December 1948.

(ii) It cannot be over-emphasized that since 1948, many countries particularly independent African Nations promulgated their own Constitutions and inserted provisions of human rights after the manner of the Universal Declaration of Human Rights of 1948. For example, the Universal Declaration of Human Rights is reproduced as Chapter IV of the Constitution of the Federal Republic of Nigeria of 1999. As a matter of fact, the impact of the Universal Declaration of Human Rights of 1948 has really been global. Hence, A. H. Robertson and J. G. Merrils have observed at page 29 of their book titled *Human Rights in the World* Manchester University Press, 1996, as follows: ‘it [the Universal Declaration of Human Rights] has greatly influenced more than forty State constitutions ... and examples of legislation quoting or reproducing provisions of the Declaration can be found in all continents’.

It is my belief that if principles are proclaimed by the United Nations General Assembly, it is most likely that all countries of the world would feel bound by them and would therefore insert them in their Constitutions or reproduce them in their important legislations.
Suggested Declaration by the General Assembly of the United Nations

In view of the foregoing, I wish to suggest as follows:

Now, therefore,

The General Assembly of the United Nations proclaims this Universal Declaration on Bioethics and Human Rights as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these principles, norms and rights and by progressive measures, national and international, to secure their universal and effective recognition and observance among all the peoples of Member States and their various organs and institutions.
LA DÉCLARATION UNIVERSELLE SUR LA BIOÉTHIQUE ET LES DROITS DE L’HOMME, SON APPLICATION ET SON AVENIR : ÉLARGISSEMENT, APPROFONDISSEMENT ET ÉVENTUELLE ÉVOLUTION JURIDIQUE

M. (Prof.) Héctor Gros Espiell,
Ambassadeur d’Uruguay en France et auprès de l’UNESCO
Membre du CIB

Schéma

I

1. Portée de cette présentation. Elle n’entre pas dans l’analyse des principes proclamés dans la Déclaration (art. 3-17, 26 et 27), ni n’aborde la question novatrice et plausible de la responsabilité sociale de la bioéthique (art. 14).

Elle se limite à traiter ce qui concerne l’application de la Déclaration universelle sur la bioéthique et les droits de l’homme et son avenir.

II


La bioéthique en tant que matière du droit international.

Universalisme et régionalisme en ce qui concerne le traitement international de la question de la bioéthique

3. Droit déclaratoire et droit conventionnel dans le droit international en matière de bioéthique. Situation actuelle. L’avenir possible.

La responsabilité sociale qu’implique la bioéthique. Son rapport avec les droits de l’homme, en particulier les droits économiques et sociaux.


7. La Déclaration universelle sur la bioéthique et les droits de l’homme et la situation des pays en développement (art. 15), de la femme (préambule, paragraphe 20), des groupes humains les plus vulnérables et des communautés indigènes (préambule, paragraphes 20 et 21).

8. Le titre de la Déclaration :
   – universelle
   – les droits de l’homme
   – signification
   – normes et principes – les raisons, à ce propos, de la modification du titre de la Déclaration.

III

9. L’application de la Déclaration :
   (a) Par l’UNESCO :
      • Diffusion des principes ➔ art. 25
      • Promotion des principes ➔ art. 25
      • Les compétences de la Conférence générale (paragraphe 5-c), de la résolution de la Conférence générale qui a adopté la Déclaration
         – Les compétences du Directeur général (paragraphe 5-a), de la résolution de la Conférence générale qui a adopté la Déclaration.
         – Les compétences du CIB et du CIGB.
   (b) Par les États :
      • art. 1 b.
      • art. 22-23.
      • Coopération entre les États – art. 24.
   (c) Autres intéressés qui doivent appliquer la Déclaration
      • Art. 1 b, 21.
• Résolution de la Conférence générale qui a adopté la Déclaration, paragraphe 4.
• Le système international en vigueur. Les Nations Unies et les organismes spécialisés.
• La société civile.
• Les professionnels, scientifiques, médecins, etc.
(d) Les comités d’éthique, art. 19

IV

L’avenir de la Déclaration :
(a) Sa nécessaire actualisation en fonction du progrès scientifiques et technologique ;
(b) Le changement social et idéologique ;
(c) Le futur travail de l’UNESCO à ce sujet :
   – Extension thématique ;
   – Réflexion sur des questions actuelles de bioéthique non abordées dans la Déclaration et émergence de nouvelles questions entraînant de nouvelles exigences et nécessités ;

UNESCO AND UNIVERSAL PRINCIPLES IN BIOETHICS: WHAT’S NEXT?

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1. Introduction

Following the adoption of the Universal Declaration on Bioethics and Human Rights, it is imperative to take positive steps to promote the principles set forth in this Declaration. Although the Declaration addresses mainly the States as expressed in Article 1, the Declaration also provides guidance to decisions and practices by relevant individuals, groups, communities, institutions and corporations, public and private.

The implementation of the Declaration is broadly expressed in two sections of the Declaration, namely, ‘Application of the principles’ (Articles 18, 19, 20, 21) and ‘Promotion of the Declaration’ (Articles 22, 23, 24, 25).

In what follows, we shall propose a number of activities for implementation describing ‘What to do?’, ‘How to do it’. These and other proposed activities should be subjected to extensive debate in each State before they are expressed in a final format of guidelines for implementation with four components: ‘What to do?’, ‘How to do it?’, By whom will it be done?’ and ‘For whom is it intended?’.

Needless to say, the ‘For whom?’ component shall include States, UNESCO (IGBC, IBC, national bioethics committees), relevant educational, research, and professional institutions, media (press, radio, TV), etc.

2. Ethics committees

First and foremost, each State should establish an independent, multidisciplinary and pluralist ethics committee (if not already established).
Among the responsibilities of such a committee as expressed in Article 19, it is imperative to stress its contribution ‘to the preparation of guidelines on issues within the scope of this Declaration’, and its ‘fostering debate, education, and public awareness of, and engagement in, bioethics’. Specific activities in this context are given below. Needless to say, these activities are addressed to the States and relevant actors with participation of international and regional intergovernmental organizations and international, regional and national non-governmental organizations (as stipulated in Article 23).

3. Dialogue and debate on bioethical issues

The words ‘dialogue’ and ‘debate’ appear in several articles of the Declaration:
- Article 2 (v): To foster multidisciplinary and pluralistic dialogue about bioethical issues etc.
- Article 18 (b): Persons and professionals concerned, and society as a whole, should be engaged in dialogue on a regular basis.
- Article 18 (c): Opportunities for informed pluralistic public debates, seeking the expression of all relevant opinions, should be promoted.
- Article 19 (iv): Foster debate, education, and public awareness of, and engagement in, bioethics.

Hence, dialogue and debate in each State should take priority and precedence among all activities of promotion and/or implementation. It is believed that there is no need to hold a debate on every principle of the Declaration, since some principles meet, by their nature, wide public acceptance. Perhaps the optimum approach is to hold dialogues or debates on selected specific issues that arise in the implementation or promotion of certain principles. The following may be proposed as a subset of these issues, with the understanding that natural differences exist among different States in the degree of importance of these issues.

3.1 ‘Intellectual property’ in the context of Art. 2 (vi): ‘to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and rapid sharing of knowledge,...’

3.2 ‘Interests and welfare of the individual should have priority over the sole interest of science and society’ (Art. 3 (b)): discussion of situations which distinctly favour interest of science and society.

3.3 ‘For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.’ (Art. 5): What special measures will be acceptable?
3.4 What modalities will be acceptable for withdrawal of consent? (Art. 6 (b)).
3.5 What exceptions to the withdrawal of consent will be acceptable? (Art. 6 (b)).
3.6 What are the modalities of ‘collective community agreement’ as a substitute for an individual’s informed consent? (Art. 6 (c)).
3.7 It will be necessary to establish a specialized unit to exercise expert judgment in situations arising from interpretation of this paragraph e.g. ‘if there is no research alternative of comparable effectiveness with research participants able to consent’. (Art. 7 (b)).
3.8 What forms of special human vulnerability are acceptable? (Art. 8).
3.9 ‘To the greatest extent possible, such (personal) information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.’ What exceptions to the protection of privacy and confidentiality will be acceptable? (Art. 9).
3.10 What are the expected forms for improper inducements to participate in research? (Art. 15).
3.11 What are the expected aspects of the ‘impact of life sciences on future generations?’ (Art. 16).
3.12 Are there any traditional practices that could be contrary to human rights in certain cases? (Art. 17).
3.13 ‘Declaration of all conflicts of interest’, ‘Use of best available scientific knowledge and methodology’ and ‘addressing and periodically reviewing bioethical issues’, (Art. 18 (a)): What modalities of all conflicts of interest will be acceptable? Will there be a specialized institution or group that will judge whether the best available scientific knowledge and methodology has been used? How frequently a review of bioethical issues will be needed?
3.14 What processes will be acceptable for promotion of ‘appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies’? (Art. 20).
3.15 What ‘appropriate measures will be acceptable to combat bioterrorism, illicit traffic in organs, tissues and samples, genetic resources and genetic related materials?’ (Art. 21 (c)).
3.16 What preparations ahead should developing countries make to optimize their opportunities of ‘entering into bilateral and multilateral agreements to build up their capacity in generating and sharing knowledge, the related know-how and benefits thereof?’ (Art. 24 (b)).
3.17 Limitation on the application of the principles (Art. 27): the article delineates four limitations, namely:
   a. in the interests of public safety;
   b. for the investigation, detection and prosecution of criminal offences;
   c. for the protection of public health;
   d. for the protection of the rights and freedoms of others.

Are these four limitations acceptable? Is there need for further elaboration on each of these limitations? What other limitation, if any, need to be included?

3.18 In addition to above specific bioethics issues arising from certain articles in the Declaration, there shall be need for continued dialogue and debate on additional bioethical issues which might arise from new emerging research activities and emerging associated technologies.

4. Education (Article 23)

Education on bioethics, particularly on the principles set forth in the Declaration, could be introduced through the following actions:
4.1 Introduce bioethics educational material at the secondary level;
4.2 Through e-learning, introduce a course on bioethics education with special emphasis on the principles set forth in the Declaration;
4.3 Produce audiovisual material for the support of educational material on bioethics.

5. Training programmes on bioethics education (Article 23)

5.1 The preparation and implementation of training programs for bioethics teachers at both secondary and university levels.
5.2 The preparation and implementation of training programs for relevant actors among individuals, groups, communities, institutions and corporations.

6. Public information (Article 23)

6.1 Publication of brochures highlighting the principles set forth in the Declaration.
6.2 Organization of lectures, seminars, panel discussions at the international, regional and national levels.
6.3 Drafting of the simplest and most explicit commentary on each article of the Declaration.
6.4 Translation of the Declaration into a large number of languages.

7. **Solidarity and cooperation**

7.1 Holding bilateral and multilateral agreements among States to organize transnational practices (Art. 21) and for the sharing of benefits (Art. 15) ensuring consistency with the principles set forth in the Declaration.

7.2 Holding bilateral and multilateral agreements among relevant research institutions to regulate transnational practices (Art. 21) and to foster the sharing of benefits of scientific research and its applications (Art. 15) ensuring consistency with the principles set forth in the Declaration.

7.3 Organizing international and regional workshops aimed at providing a standard framework of legislation and regulations for the implementation of principles set forth in the Declaration.

8. **Enacting or developing national (domestic) bioethics legislation or policies**

In his address to the second session of the Intergovernmental Meeting of Experts (UNESCO, 20 June 2005) the Director-General of UNESCO stated three interdependent objectives for the expected Declaration, namely,

- ‘to produce a text of practical use that will guide States in drafting legislation and formulating policies’;
- ‘to contain the principles and procedures implemented by persons, groups and institutions concerned with bioethics’;
- ‘to encourage dialogue within societies on bioethics issues and the sharing of knowledge in science and technology’.

It is hoped that each State shall end up drafting a legislation and formulating policies as a consequence to all application and implementation activities stated above, in addition to any other activities deemed appropriate. It is indeed imperative that a national law on bioethics be enacted in each State, which indeed will put into operation the principles set forth in the Declaration, in direct response to the preambular statement that: ‘Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law’.
9. Follow-up of the Declaration

Article 25 states that ‘UNESCO, with the assistance of the intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC) shall promote and disseminate the principles set forth in the Declaration’. Needless to say, UNESCO will play an important role in the activities stated above (education, training, public information, debates). Furthermore, for the purpose of follow-up, UNESCO could undertake the following two responsibilities:

9.1 monitoring the commitment of States on the implementation of the principles set forth in the Declaration;
9.2 formulating opinions or proposals for further effectiveness of the Declaration, and hence, making recommendations addressed to the General Conference.

10. Evaluation of the Declaration

It was felt inappropriate that the Declaration shall include the foreseen mechanisms for reporting or periodic review (Final Report of the Second Session of the Intergovernmental Meeting of Experts, 20-24 June 2005). However, it is believed that it is still the responsibility of UNESCO to evaluate periodically the implementation of the Declaration, perhaps through quantitative and/or qualitative assessment of:

10.1 the degree to which the principles set forth in the Declaration are implemented;
10.2 the impact of the Declaration in the areas of:
   - public debate
   - public awareness
   - national legislation.
10.3 practices which are contrary to the principles set forth in the Declaration.

It is expected that such evaluation be examined at a joint session of IGBC and IBC, and hence, submitted with recommendations of the two Committees in accordance with the procedures established by UNESCO.
SESSION II
“UNESCO DECLARATIONS IN THE FIELD OF BIOETHICS AND CULTURAL DIVERSITY”

- Mr (Prof.) Patricio Ventura Juncá (Holy See)
- Mr (Prof.) Tomoaki Tsuchida (Japan)
- Mrs (Prof.) Nouzha Guessous-Idrissi (Morocco)
- Mr (Prof.) Michel Revel (Israel)
- Mr (Dr) Roberto Andorno (Argentina)
UNITY AND DIVERSITY IN NATURE:  
MOVEMENT AND IDENTITY IN HUMAN BEINGS  
KEYNOTE ADDRESS

Mr (Prof.) Patricio Ventura Juncá,  
Member of the Governing Council,  
Pontificia Academia Pro Vita, Holy See

Universality and cultural diversity recall the time when the Greek philosophers marvelled at the unity and diversity found in nature. Existence occurs in many different ways. That great community and unity in the marvel of being, of existing, melded with the marvel of the diversity of things, of living and non-living beings, of the diversity of species and finally of individuals. Among humans, diversity occurs at different levels: ethnic, geographic, historical. These aspects of cultural diversity are distinct from, but also bear the imprint of, the diversity of individuals. How to comprehend unity and diversity remains one of the key issues of philosophy. All things have something in common and something diverse.

The Greeks also studied the problem of movement, of change, in nature and especially in the development of living beings. They asked: how can something change and yet be still the same? This is no longer a question of the unity and diversity of things, but also of the differences that movement makes in the same individual. Aristotle, a philosopher and biologist, shed much light on the background and conditions of the fact known to everyone that living beings have a beginning, a period of development, and an end. They are born, they grow, and they die. Here the question was: how can the same individual change, grow, develop, while retaining its innermost identity? This is an admirable, astonishing fact that, as a paediatrician, I have witnessed daily. Children grow; they change, while retaining their fundamental identity as human beings, individuals, descendants. It is the history of all of us: without a trans-temporal identity we would have no history.
From Potter to the UNESCO Declaration

The Greeks also asked a more specific, ever-present question: the question about human beings. The oracle at Delphi bears the inscription: ‘Man, know thyself’. This saying elucidates the ‘unique capacity of human beings to reflect upon their own existence’\(^1\) and seeks a response to the questions: What is man? Who am I? The latter is an existential, rather than theoretical, question that has come down to us through the centuries in different forms. Who am I? What is the meaning of my life? Today perhaps the cry is more insistent, at times full of anguish, and with the progress of science and technology, especially of the life sciences, it has acquired a new dimension.

With visionary intuition, Van Rensselaer Potter wrote in 1971: ‘Mankind is urgently in need of a new wisdom that will provide “knowledge how to use knowledge” for man’s survival and for the improvement in quality of life.’ I take the position that the science of survival must be built on the science of biology and enlarged beyond the traditional boundaries to include the most essential elements of the social sciences and humanities with emphasis on philosophy in the strict sense, meaning ‘love of wisdom’. I therefore propose the term Bioethics in order to emphasize the two most important ingredients in achieving the new wisdom that is so desperately needed: biological knowledge and human values\(^2\).

The Universal Declaration on Bioethics and Human Rights embodies the ideas expressed by Potter: ‘Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments’ and further: ‘Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity’s response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment.’

The question about man gains new perspectives today; the understanding of life reaches new dimensions; the sense of development at a dizzying speed raises new questions and urgently requires answers. Globalization throws into relief that Potter’s words are increasingly applicable to most nations and cultures. Scientific and technological progress needs to coa-

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lesce into a truly human form of development. The innermost aspirations of the human heart reach out for new answers in this novel scenario.

Universality and cultural diversity: is this possible?

In the field of bioethics, the issue of universality and cultural diversity might appear to be a contradiction in terms. Is a Universal Declaration on Bioethics and Human Rights compatible with cultural diversity? We must begin by stating that cultural diversity exists: it is a fact, recognized today as a great wealth for humankind. The UNESCO Declaration on Cultural Diversity points out that cultural diversity is embodied in the uniqueness and plurality of the identities of groups and societies making up humankind. As a source of exchange, innovation and creativity is necessary for humankind. In this sense, it is the common heritage of humanity and should be recognized and affirmed for the benefit of present and future generations.’ Pope John Paul II, referring to the crucial importance of the much needed dialogue between cultures for a civilization of life and peace, stated: ‘Reflecting upon the human situation, one is always amazed at the complexity and diversity of human cultures’\(^3\).

Along the same line of thought, cultural diversity should be recognized as part of human rights. Historically, cultures have developed within a specific geographic territory and, as a result, cultural rights are often equated with the right of each nation to exist in independence, including its ‘proper language and culture and the right to shape its life according to its proper traditions, excluding all abuses of human rights, particularly those of minorities’\(^4\). On the other hand, cultural, ideological, and religious diversities have fostered major conflicts, and have been used to justify some of the most outrageous violations of fundamental human rights. Our task then is first to outline what is universal, valid for all cultures, and then how to understand cultural diversity vis-à-vis such universality.

**Universality in bioethics**

The opening clause of the Universal Declaration on Bioethics and Human Rights states: ‘Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment; to perceive

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injustice; to avoid danger; to assume responsibility; to seek cooperation and to exhibit the moral sense that gives expression to ethical principles’. In these concepts we can find an initial approach to universality. They also serve as foundation for the rest of the Declaration. This first reference to universality brings us into the sphere of a diversity simultaneously viewed from many angles. The UNESCO Declaration was the result of a lengthy and fruitful dialogue, in which representatives of many countries and cultures took an active part. Thus, from this diversity arose a universal declaration that should become paramount in helping people to deal with complex and ever-increasing bioethical dilemmas.

It must be stressed, however, that many human beings have not developed the faculty of self-reflection, or have lost it, and that those who do enjoy such a faculty are responsible for the noble task of recognizing and protecting the dignity of such incompetent and vulnerable human beings. This issue is covered in the Declaration.

In both experimental science and philosophy, the human spirit always seeks universality. Bioethics is no exception. In many senses, ethics is undoubtedly a very complex and sensitive area. Ethics deals with right and wrong, with our behaviour, our private life, our relations with others and also with relations inside or outside national and international communities. Ethics likewise seeks to identify and retrieve the basic human good that causes individuals, communities and peoples to lead flourishing lives, together with the evil that interferes with the possibilities of human fulfillment. Aristotle was aware of the difficulty: we always pursue goodness, what is good, but we find it hard to distinguish between the ‘truly good’ and the ‘apparent good’. Owing to the particular circumstances in which human action takes places, such as emotional issues, conflicts of interest, or cultural customs, the distinction is often difficult to make. There is an additional mystery: very often, humans know what is good but fail to act consequently. Saint Paul admits, sadly: ‘The good that I would I do not: but the evil that I would not, that I do’ (5). These words eloquently describe the perplexity that stems from our moral incoherence and emphasizes the complex nature of moral life for individuals and communities. Notwithstanding, the recognition of universal principles is already a major historical achievement. We have a light to guide us, even if we sometimes stray from the right path.

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5. St Paul, Epistle to the Romans 7, 19.
The first and basic universal principle established in the UNESCO Declaration is that of human dignity. This concept is the corner stone that supports the other principles – like respect for life and informed consent. In this regard, the UNESCO Declaration is consistent with the opening lines of the United Nations’ Universal Declaration of Human Rights: ‘Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world’(6). The Universal Declaration on Bioethics reemphasizes this fundamental notion: ‘Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms’. In this context, allow me to quote Mrs Michele S. Jean, Chairperson of the International Bioethics Committee (IBC): ‘Human dignity is a notion that crops up in several international texts, notably in the Universal Declaration of Human Rights, and in the works of philosophers like Kant. ‘This principle has the advantage of putting forward a vision of the human being. If we don’t take human dignity into consideration, what is the use of talking about principles like autonomy or informed consent?’(7).

Human dignity is the origin of respect for human rights and fundamental freedoms. These three principles are interlinked and essential for understanding other more specific principles included in the Declaration.

Cultural diversity and bioethics

Human dignity is a value of the highest order and despite cultural differences it is recognized worldwide. Possibly, however, in different cultures it may be understood from different perspectives and with different degrees of emphasis. The same may apply to other more specific principles of the Declaration, giving rise to the need for intercultural dialogue designed to enrich the notion of human dignity and other principles in the Declaration. Such discussion may be approached in original ways, but violation of the essence of those principles can never be justified on the grounds of cultural diversity(8). In the same context, may I again quote Mrs Jean: ‘We must not

8. ‘The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental.’ (Art. 12).
fall into any kind of cultural relativism, where everything is mixed up and we can do anything in the name of cultural diversity. This is why we specify in the declaration that one cannot undermine the values of justice, human dignity and human rights in the name of cultural diversity. An intercultural dialogue can help to enrich our understanding of the principles. Within this context, the words of Pope John Paul II to the United Nations remind us that every culture has something to teach us about the truth of man and the mystery of human existence. Thus our answer to the question whether it is possible for universality and cultural diversity to be joined together must be a positive one.

This positive view notwithstanding, I would like to make it clear that we cannot ignore the serious problems arising from tensions among different cultures, ethnic groups and peoples. History has witnessed countless human sufferings caused by senseless and brutal efforts to impose foreign cultures, ideologies and religions. In addition, new challenges must be faced today, arising – for instance – from migrations, which originate cases of cultural diversity in new settings and for which no easy solutions are readily available. Here, again, intercultural dialogue must be promoted and valued. This does not mean losing cultural identity, but rather opening fearlessly to the rich content of other cultures. If diversity includes the sincere pursuit of truth and not imposition by any form of pressure, the force of the truth will always prevail.

Different ethnic roots, customs, traditions and life styles are initial barriers for intercultural dialogue, but progress is assured when, with openness and trust, we use our differences as a way to a deeper understanding of the mystery of human existence and human dignity.

Here I would like to pause for a moment in order to clarify the differences between cultural diversity and varying ethical and anthropological views. Though, admittedly, cultural biases may be involved in such differing opinions, a distinction has to be made. Indeed, different ethical and anthropological views may exist within the same culture, more often than not originating bitter arguments and debates in the field of bioethics, particularly in matters concerning the beginning and end of life. But the question of the truth of these opinions must never be reduced to a mere question of cultural differences. ‘We must not fall into any kind of cultural relativism,

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9. Interview with Mrs Michèle S. Jean, op. cit.
where everything is mixed up and we can do anything in the name of cultural diversity."(11)

**Beyond rights: the need for solidarity**

Cultural diversity is very often associated with socio-economic conditions and status. In vast regions of the world, extreme poverty is still highly prevalent and therefore hundreds of millions of human beings are deprived of progress, knowledge and education. Worldwide inequities among and within countries pose significant ethical problems of solidarity, imperatively requiring a reorientation of global economics, ranging from military defence to education, housing and food production. In most developing countries, many complex ethical decisions derived from modern medicine and biology are irrelevant and practically fail to arise. Other health and ethical priorities including poor sanitation conditions, outbreak of epidemics, and malnutrition, are far more pressing. The fact that millions of children around the world are still not immunized against measles, a major cause of death and morbidity in infants, is a dramatic and eloquent reminder of this sad state of affairs. These cultures very often show noteworthy marks of solidarity, affection and respect for life and for more vulnerable individuals or those unable to fend for themselves.

In sharp contrast, western-style civilizations often tend to value people only for their efficiency, their productive ability. This, together with extreme individualism, many times leads to loneliness, anxiety and inner emptiness. In many ways this type of emotional and spiritual deprivation represents an oppressive type of poverty.

These cultural realities are an invitation to think about humankind not only in terms of rights, but also of ultimate fulfilment. Respect for basic rights and technological progress is not enough for the human heart to experience its own worth, dignity, and the impulse to share. Here I mean the human heart as a symbol of our inner core, our centre, as the Greeks believed. Article 13 of the Declaration stresses solidarity and cooperation. Mother Theresa of Calcutta, speaking of a civilization of peace and love, said that she was increasingly convinced that lack of love is the worst ill that a human being can undergo, adding that medicine can cure many and complex dis-

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11. Interview with Mrs Michèle S. Jean, op. cit.
eases, but unless there are hands ready to serve and hearts disposed to love, the sickness of not being loved will be incurable.

**Protecting future generations**

Protecting future generations is an issue that involves both universal principles and the notion of respect for cultural diversity. Article 16 of the UNESCO Declaration points out ‘the impact of life sciences on future generations, including on their genetic constitution’. This is a clear reference to the possibility of human genetic manipulation and potential threat to diversity. However, in addition to biology, we need to consider other conditions that are essential for the full development of human beings in their original diversity. I firmly believe that we must protect the right of future generations to develop under conditions that will enable them to retain their own identity and achieve full development. In this context, may I again quote the words of John Paul II: ‘The need to accept one’s own culture as a structuring element of one’s personality, especially in the initial stages of life, is a fact of universal experience whose importance can hardly be overestimated. It is on the basis of this essential relationship with one’s own ‘origins’ – from the standpoint of family and also of territory, society, and culture – that individuals acquire a sense of their nationality, and culture’.12

Future generations arise from the birth of new human beings. Responsibility for their future is also an issue in bioethics; not only for their biological future but also for their human development, to which end it is necessary to protect the fundamental settings that allow the child to develop, including first of all the family and the particular cultural conditions of the original culture where the child develops.

The birth of each new child is objectively a sign of hope for it augurs the possibility of improving the human condition. I would like to conclude with a text from the Jewish philosopher Hanna Arendt that sums this up in very beautiful words: ‘The miracle that saves the world, the realm of human affairs, from its normal, ‘natural’ ruin is ultimately the fact of natality. It is, in other words, the birth of new men and the new beginning, the action they are capable of by virtue of being born. Only the full experience of this capacity can bestow upon human affairs faith and hope, those two essential

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characteristics of human existence. It is this faith in, and hope for, the world that found perhaps its most glorious and most succinct expression in the few words with which the Gospels announced their glad tidings: ‘A child has been born unto us’\(^{13}\).

In this same direction, let me finish quoting the United Nations Declaration of the Rights of the Child: ‘Whereas mankind owes to the child the best it has to give’\(^{14}\).


Many types of bioethics reflect different cultural traditions, while sharing common concerns for human health, well-being and peace

Bioethics in Japan, which started in earnest around 1980, has been steadily and robustly developing. It now involves many more people in ever-wider areas of concern about human life, health and welfare as well as about what is humanity itself in such biomedical advancements as the evolution of assisted reproductive technology and brain sciences.

At its outset, our bioethics was greatly influenced by its American counterpart with the latter’s stress on the autonomy of individual persons and with its principle-based approach on ethical issues. There were skeptical views in Japan concerning these characteristics of U.S.-born bioethics. Of course the autonomy of individuals is vital and indispensable in choosing from among plural medical treatments or rejecting treatment without control or coercion from somebody else or some institution, including doctors. Yet there is doubt whether autonomy should be given the highest priority vis-à-vis the wishes of the loved ones or whether autonomy should in any case be forced on a patient, to such an extent as to commit acts against life.

In Japan, the family has been regarded as the very basis of human life upon which individual identity and well-being were considered to depend. Individualist decision-making concerning life and death matters, on the other hand, might jeopardize the family unity and consequently society at large and, as a result, threaten each person’s well-being. Death is not an individual’s affair but a serious concern of the family or community. Look,
for example, at the fact that among the Japanese there is still reluctance among the majority of people to regard the brain-dead to be dead as a person, or that in Japan the family’s opinion is decisive for agreeing to the donation of organs and tissues from the brain-dead, even when the latter has indicated his or her wish to do so. Consider another example that in this country, donation of a section of the liver or a kidney from a living and healthy member of a family to another within the same family is peculiarly frequent compared with the very rare donation of organs from brain-dead donors.

In addition, the shape and the status of ethics are quite different from those in the Western world. Japanese people have had a peculiar history of cultural and other isolation over so many centuries, being situated on the eastern-most periphery of the Old World, such that their cumulative tradition has nurtured their own religio-cultural ethos so thick as to make them feel it unnecessary to work out a theoretical intellectual examination, namely an ethics, out of this ethos. Besides, we did not have one united church or religion such as might have helped form a moral theology or ethics. All historical, cultural differences notwithstanding, we have entered this global technological civilization; and like other peoples, we need a new ethical awareness vis-à-vis biomedical progress whose effect could most likely be ambiguous: helping our health greatly as well as testing humanity so profoundly. Besides, Japanese society has gone through tremendous changes. Most significant of the changes with regard to morality derives from the fact that the society has been greying so fast, in a way unprecedented in our history and rare in the world, with the longevity extending by 30 years over half the century since the end of the World War II and the birth rate decreasing rapidly. Our population is now on the decline; and at the same time, our society is getting more and more interlocked with other nations and societies, our culture much more diversified than ever.

We are now keenly aware that our moral concern and act will be affecting not only ourselves but also other peoples. It is vital for us, therefore, to reflect on our traditional ethos, or on its rapid crumbling and fading, and come up with a new ethics.

We need practical and professional ethics to ensure a sound humane evolution of this civilization, which is dependent on the ever-developing science and technology. Of these, bioethics is central for its direct impact on the life and well-being of each individual person and communities, not only in Japan but also elsewhere. We need a cosmic or universal awareness beyond interests of particular individuals, societies and nations, so as humanely to respect the very basic dignity of each individual person.
In many other ways too, our society is much indebted to and bound by our own tradition, and yet the societal conditions and our ways of thinking as well are changing: ethos too is historically malleable. At the same time, our age of technological civilization urges us to ponder how better, if not quite at the best, we could remain humane or keep the planet in good shape for posterity. After a secularist and rationalist age, we may become aware of the oneness of human beings once again, may be able to share the awareness, thanks to the scientifically supported knowledge about the impact of our deeds on our own posterity and other beings on the planet and thanks to the technological feat of bringing diverse peoples and cultures into contact and collaboration.

We have now in Japan thousands of physicians, nurses, clinical psychologists, medical social workers, philosophers, religionists, and many other teachers engaged in bioethics research and teaching and many study groups pursuing bioethics here and there other than two major academic associations dedicated to bioethics. With the cultural diversity on the one hand and universal human dignity on the other, we need to seek a new synthesis through constant learning together, through research and discussions.

Bioethics is primarily an ever-evolving process of education and discourse among people and peoples.

As biomedical science and technology do not cease to develop and their impact on beings is ever-increasing, we need to have specialist professionals as well as common citizens to sense their ethical, legal and social implications and work out solutions to them through research and discourse. For this process I would like to suggest three points for our consideration.

1) Guided by the Universal Declaration on Bioethics and Human Rights, we should promote research and education in bioethics. Ethics is none other than this process of critical examination of potential problems, violations of human rights and health hazards, etc. and the education about them mutually concerned with human dignity. Ethics committees should be invigorated and made accessible in appropriate ways, and education should be promoted at schools and in the various social organizations.

2) Ethics should not be reduced to mere pieces of knowledge, know-how or information about rules and guidelines. It should encourage every individual, specialist or lay person, to face and prepare for human conditions of life, disease, ageing and death. Ethics is practicing with one’s intellect and love, one’s own reason and compassion for others; it is concerned not only about technical knowledge of things or about mere situations, but also
about one’s own and neighbours’ humane existence in this world, the only planet we share.

3) Lay people should be encouraged to take part in the care for the sick, the debilitated and the weak as volunteers. We now see hundreds of people working as hospital volunteers, or in case of disaster, volunteer helpers working in this country and abroad. To get involved in medical and health care, we not only develop our sense of common humanity, vulnerable to illness, accidental injury, ageing and after all death, but also we develop solidarity among people within the technological civilization which tends to isolate us from the universe, other persons and other beings inside the walls of steel and concrete and networked virtual reality.

We bring our own traditionally nurtured sensitivity and ways of thinking to bioethics discourse. Let’s continue to critically examine ourselves and exchange views with other viewpoints. Cultural diversity in response to bioethics problems can lead to progress in universalist understanding.
Les Déclarations de l’UNESCO en Matière de Bioéthique et la Diversité Culturelle : l’Exemple du Maroc

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bioéthique, et cela en conformité avec l’article 26 de la Déclaration universelle sur la bioéthique et les droits de l’homme qui affirme l’interdépendance et complémentarité des principes.

Et cela soulève la question de savoir si les principes universels de droits humains et bioéthique existent en soi et font consensus, ou bien s’ils sont ou peuvent être issus d’un consensus, sans forcément être d’accord sur les fondements de cet accord : raison, foi, culture, croyances, traditions, etc. ; ce qui laisserait la place à des applications différentes adaptées au contexte culturel. Quelle(s) réponse(s) peut-on proposer à la question de l’universalité des droits humains au regard de la diversité culturelle sans tomber ni dans un impérialisme culturel qui imposerait un modèle prêt et indiscutable de pensée et d’action en matière d’éthique, ni dans un respect dogmatique de la diversité culturelle qui tolérait des pratiques contraires aux droits humains au nom du respect des cultures ? Comment gère-t-on ce dilemme dans le contexte du Maroc ?

**Quelques données sur le contexte sociopolitique marocain**

Le Maroc est un état arabo-berbère, membre de l’ONU et de l’UNESCO, qui a ratifié les pactes et conventions des Nations Unies, politiquement en phase de transition démocratique, souscrivant aux principes universels de droits humains comme le stipule le préambule de sa Constitution de 1992 et celle de 1996 qui est encore en vigueur, qui affirme « L’attachement du Royaume aux droits humains tels qu’ils sont universellement reconnus ». A noter que les débats actuels visent à faire inscrire ces clauses dans le corps de la Constitution qui est objet de demande de révision ; et ce pour leur donner encore plus de poids. Par ailleurs, la même Constitution déclare l’Islam comme la religion de l’État, mais en pratique, face à la montée de fondamentalismes religieux aussi bien au plan national qu’international, il y a une politique affichée et déclarée de protection et promotion d’un Islam modéré et ouvert sur la modernité, comme en témoigne l’adoption du nouveau Code de la famille en février 2004. Néanmoins, du fait de la sensibilité religieuse de certaines questions bioéthiques telles celles touchant à la sexualité, la filiation ou les relations familiales (à l’exemple des nouvelles techniques de procréation médicalement assistée, statut de l’embryon, contraception et avortement), et du risque de leur exploitation et instrumentalisation par des mouvements politiques prenant leurs références exclusivement dans une certaine vision de la religion, on note une certaine « frilosité » des décideurs sur les questions de bioéthique qui se manifeste notamment par l’absence d’une réglementation nationale claire et plus généralement par le peu et/
ou pas d’institutionnalisation ni de loi bioéthique. Concrètement, malgré l’insuffisance d’accès aux soins de santé de base qui se reflètent au niveau des indicateurs nationaux de santé (voir encadré N°1, il faut signaler que ces données ont été actualisées depuis à l’occasion de la publication en 2006 du Rapport du cinquantenaire de l’indépendance sur le développement humain), on note le relatif développement de nouvelles techniques médico-biologiques (PMA, FIV, ICSI, tests génétiques, greffes d’organes et tissus...) mais dont l’accès reste très sélectif du fait de leur coût. Et devant l’absence ou l’insuffisance de réglementations nationales, leur pratique reste tributaire de l’éthique personnelle des professionnels, vu qu’il n’y a toujours pas de comité national ni de comités hospitaliers de bioéthique, seulement deux comités autoproclamés d’éthique de la recherche biomédicale, et récemment une Association marocaine de bioéthique qui a été créée à l’initiative de professionnels dans les domaines de la santé, la recherche, et d’activistes de la société civile.

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<tr>
<th>Encadré n° 1</th>
<th>Encadré n° 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quelques données significatives sur la santé au Maroc</strong></td>
<td><strong>Principales problématiques bioéthiques au Maroc</strong></td>
</tr>
<tr>
<td>Population 29 millions</td>
<td>Offre de soins de niveau approprié (94)</td>
</tr>
<tr>
<td>Budget de la santé / budget général 4.5%</td>
<td>Équité dans la disponibilité et l’accès aux soins (126) ➔ médecine à plusieurs niveaux</td>
</tr>
<tr>
<td>Budget de la recherche/ PIB 0,8%</td>
<td>Éthique de la relation soignant soigné (152)</td>
</tr>
<tr>
<td>Dépenses de santé / habitant / an 50 USD</td>
<td></td>
</tr>
<tr>
<td>Nombre de médecins/ habitant 1/2084 (839-4587)</td>
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</tr>
<tr>
<td>Lits d’hospitalisation/habitant 1/1118</td>
<td></td>
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<td>Couverture/assurance-maladie &lt; 15%</td>
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<td>Taux de mortalité maternelle 228/100.000</td>
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<td>Probabilité de décès avant 5 ans 6.5%</td>
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<tr>
<td>Espérance de vie à la naissance 66 ans</td>
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*Classement par l’OMS en 2000 sur 191 pays selon le degré et distribution de la réactivité qui évalue des paramètres relatifs au respect de la dignité, autonomie, information, confidentialité, efficacité et humanité des soins*

**Sources :** rapport OMS, 2000; Ministère de l’Économie et des Finances et Ministère de la santé Maroc, 1999, 2000, 2001
Cela amène deux constats majeurs :

– le premier est celui de l’existence d’une médecine et santé à plusieurs niveaux qui fait que les principales problématiques éthiques au Maroc restent liées à l’accès équitable à des soins de santé de niveau approprié, et à la qualité et l’humanisation de la relation soignant soigné (voir encadré N°2).

– Le deuxième concerne le respect des principes éthiques dans la pratique des activités de soins et recherche qui reste tributaire de l’éthique individuelle des prestataires, et qui génère des pratiques et attitudes individuelles contradictoires à l’échelon national, parfois même en contradiction avec la réglementation nationale quand celle-ci existe, et ce du fait des sensibilités plus idéologiques que culturelles des prestataires.

Ainsi et à titres d’exemples, alors qu’il y a une pratique ouverte et relativement libérale de la contraception qui est promue par une politique active et efficace de planification familiale avec un taux de couverture contraceptive supérieur à 60 % et un indice synthétique de fécondité des femmes qui est passé de 7 en 1962 à 2,5 en 2004. Elle est gratuite dans les dispensaires, et aucune loi nationale ne stipule la nécessité d’une autorisation maritale sauf en cas de contraception définitive. Or en pratique, certains médecins et responsables de centres de planification familiale exigent l’autorisation du mari pour une prescription contraceptive. Par ailleurs, certains chercheurs exigent le consentement du mari pour l’inclusion d’une femme dans des essais cliniques sur des contraceptifs oraux sans impact sur l’autonomie ou la dignité de l’époux. Ces pratiques sont justifiées par leurs auteurs au nom du « respect des spécificités culturelles et religieuses du Maroc, pays arabo-musulman où traditionnellement la femme est sous la tutelle de son époux. »

Or aucune loi nationale ne le stipule et même le nouveau Code de la famille a aboli le principe général de tutelle matrimoniale sur la femme majeure (article 24), et proclamé clairement la coresponsabilité des deux conjoints au sein de la famille, et notamment en matière de planification familiale (art. 51 - alinéa 4).

Sur un plan plus général, les questions soulevées par la relation entre Islam et bioéthique sont très controversées et ne justifient pas toujours les pratiques contraires aux principes universels de respect de l’autonomie et de la liberté individuelle notamment celles des femmes. En effet, vu qu’il n’y a pas d’autorité cléricale centrale qui requiert l’unanimité de tous les musulmans, ce qui à mon avis est en même temps un chance et un problème, il y a en réalité autant de compréhensions et pratiques de l’islam que de pays, groupes, situations, époques, conjonctures, etc. Il n’y a pas non plus d’ins-
lance islamique légitime (dans le sens de son indépendance et sa composition pluridisciplinaire et pluraliste) et active en matière de bioéthique. Cependant, il y a une unanimité déclarée de tous les leaders qu’ils soient politiques ou religieux sur la conformité des principes fondateurs de l’Islam avec ceux des droits humains universels. Ainsi, et toujours concernant l’exemple de la contraception, elle a été autorisée du vivant du prophète, pour la préservation de la santé de la mère contre les grossesses répétées et rapprochées, ainsi que pour réguler le nombre d’enfants en fonction des moyens économiques, et au XIIe siècle l’Imam Ghazali ajoutait « et même pour préserver la beauté de la femme ». Donc à priori, il n’y a pas de controverse possible à ce sujet au nom de l’Islam. Concernant les principes éthiques de recherches impliquant les sujets humains, une réunion regroupant des spécialistes chercheurs et des théologiens de pays musulmans s’est tenue à Genève en 2004, à l’initiative du CIOMS en collaboration avec l’OMS et avec l’Organisation islamique des sciences médicales, et a abouti à l’élaboration de lignes directrices à partir d’une perspective islamique (International Ethical Guidelines for Biomedical Research Involving Human Subjects, an Islamic perspective, disponible au site www.islamset.com/ions/code2004/Islamic_vision1.html). Ainsi la 4e ligne directrice relative au consentement éclairé affirme que l’Islam confirme le principe universel de respect de l’indépendance et autonomie de l’individu qui a le droit de consentir ou non sans aucune coercition. « The Islamic Law principle calls for respect of the independence of every individual and his right to make his personal choices and arrive at decisions suitable for him, without any trace of coercion or deception. » Et la 16e ligne directrice précise que dans le cas des femmes adultes qui se portent volontaires dans des protocoles de recherche, il faut que les investigateurs obtiennent son consentement personnel et que l’islam n’impose aucunement la permission de l’époux car cela serait une atteinte à ses droits de personne humaine. (« An investigator must obtain the personal, voluntary consent of an adult female to participate in research. In Islamic Law, it is unacceptable for the permission of a husband to replace that of his wife, because that would be an affront to her human rights, as members of both sex enjoy full competence. »)

Ainsi, il apparaît clairement que des attitudes telles que celles décrites plus haut, en plus du fait qu’elles sont en contradiction avec la réglementation interne du Maroc, sont le fait d’une interprétation instrumentaliste du respect de la diversité culturelle, en l’occurrence de l’islam selon leur interprétation, et ce au service d’une idéologie et d’un projet de société qui ne reconnaît pas le principe universel d’égalité et de dignité inhérente à la personne humaine quel que soit son sexe, sa race, son statut, etc. et cela
est aussi en contradiction avec les principes énoncés aussi bien dans la Déclaration universelle sur la bioéthique et les droits de l’homme que dans la Déclaration universelle sur la diversité culturelle.

Ainsi, on voit que pour la question de l’universalité des droits humains au regard de la diversité culturelle, la bioéthique pose, au moins, un triple défi :

1. Un défi à la communauté internationale, celui de donner corps à la notion même d’universalisme en trouvant des terrains de dialogue pouvant aboutir à un consensus par une approche pluraliste pacifique et créative, respectant la diversité et reconnaissant les divergences. Pour cela, des ponts avec le politique et le social doivent forcément être établis ; et cela jette les jalons d’une solidarité et coopération internationale admettant le principe de partage des bienfaits.

2. Un défi aux États, celui de la gestion démocratique et participative des processus de prise de décision, notamment pour la définition des priorités pour l’allocation des ressources de santé et recherche dans le respect des principes de justice et équité, égalité et non discrimination, responsabilité sociale ; en d’autres termes, la bioéthique ne peut se concevoir sans démocratie et gestion participative.

3. Un défi à la communauté médicale et des chercheurs, celui de combattre le paternalisme médical et scientifique notamment pour les principes d’autonomie, de responsabilité et de consentement ; et ce en vue d’éclairer sa pratique à la lumière des besoins et de la réalité multiple de la société, non de manière démagogique qui objectivement aboutit à un nivellement par le bas au nom des traditions et spécificités culturelles, mais plutôt dans la promotion du respect des valeurs universelles.

**Que faire pour cela ?**

D’une part, il faut diffuser et promouvoir la mise en œuvre de la Déclaration universelle sur la bioéthique et les droits de l’homme, et pour cela les États ont un rôle majeur par la prise de mesures législatives et administratives appropriées, et par la mise en place de comités d’éthique (art. 22). Tout cela doit s’accompagner d’un processus continu et évolutif d’information, sensibilisation, éducation et formation (art. 23), auprès non seulement des professionnels de santé et des chercheurs, mais aussi des jeunes et du grand public.

D’autre part, et sur un plan plus général, il faut promouvoir les principes universels de droits humains dans un respect « approprié » des diversités et spécificités culturelles (art. 12). Car comme l’écrit le Directeur général
de l’UNESCO, M. Koïchiro Matsuura, dans la préface de la Déclaration universelle sur la diversité culturelle : « ... cela vise aussi à éviter des ségrégations et des fondamentalismes qui, au nom des diversités culturelles, sacraliseraient ces différences, allant ainsi à l’encontre du message de la Déclaration universelle des droits de l’homme, et pour « ... opposer aux enfermements fondamentalistes, la perspective d’un monde plus ouvert, plus créatif et plus démocratique... ».
The Universal Declaration on Cultural Diversity of UNESCO (2001) points at a dual interdependence of human rights and cultural diversity. Article 4, entitled ‘Human rights as guarantees of cultural diversity’, proclaims that the defence of cultural diversity is an ethical imperative, inseparable from respect for human dignity. It implies a commitment to human rights and fundamental freedoms, in particular the rights of persons belonging to minorities. No one may invoke cultural diversity to infringe upon human rights guaranteed by international law, nor limit their scope. First, human rights - that are universal - guarantee the particular expression of individual cultures, being understood (as reaffirmed in the Preamble) that ‘culture should be regarded as a set of distinctive spiritual, material, intellectual and emotional features of society or a social group and that it encompasses ... lifestyles, ways of living together, value systems, traditions and beliefs’. But conversely, there is a need to protect the universality of human rights from a claim that such diverse features of societies or social groups could justify contravening human rights as guaranteed by international law. Such dual relationship indeed reflects some ambivalence in the value of cultural diversity.
But the dual relationship also stems from a difference in nature. Human rights are natural-born rights and are defined by international law, unlike culture. In the words of Hélé Béji in *The Future of Values*:\(^1\) ‘Human rights are defined as natural rights, at the opposite of cultural rights ... Human rights emerge from erasing cultural differences, from ending the hierarchy of cultures. They affirm that the cultural argument cannot claim the authority of a legal principle. All men are free and equal in rights, whatever their origin, their language, their beliefs ... Human rights are subject to a civil law that controls them and is applicable to all, whereas cultural rights are left to the free appreciation of their proponents’.

Such considerations will assuredly be of greater relevance when ethical issues are at stake and more so when these impinge upon life matters, which is the essence of bioethics. One may therefore ponder on the reason for including an article on ‘Respect for Cultural Diversity and Pluralism’ in the Universal Declaration on Bioethics and Human Rights of UNESCO (UDBHR). In the draft elaborated by the International Bioethics Committee (IBC), Article 7 stated that ‘any decision or practice shall take into account the cultural backgrounds, school of thoughts, value systems, traditions, religious and spiritual beliefs and other relevant features of society. However, such considerations shall not be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope’. In the final text adopted by the General Conference of UNESCO, the language (Art. 12) was slightly modified: ‘The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms nor upon the principles set out in this Declaration, nor to limit their scope’.

What is the importance of a principle respecting a pluralism rooted in cultural diversity when dealing with ethics of science, particularly of life sciences? Does it not deny bioethics to be, like the science it reflects upon, a set of common truths for all? Does it not contradict the need for a clear and unified line of action? Such apparent contradictions arise from the recurrent error of considering that principles are in competition with each other, that they are incompatible in essence and force us to make a choice between them. On the contrary, ‘principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances’ (Art. 26, UDBHR). This complementarity is a requirement to reach harmony. When reflecting on an issue, the principles that form the basis of the reflection may well be different and sometimes conflicting, but the essence of bioethics is
to assemble the principles to build a set of harmonious rules, in which all can acknowledge sufficient elements of truth to abide by them.

**Universality and pluralism**

The world in which we live is by nature pluralistic, an assembly of nations and cultures. The lessons of history, after the French Revolution of 1789 and with greater urgency after World War II, have led humankind to proclaim universal human rights to protect the dignity, equality and liberty of all human beings. In this wake, and particularly the atrocities of Nazi doctors, bioethics has emerged to ensure the universal respect of human dignity, human rights and fundamental freedoms for the welfare of the individual in medical practice and in the application of the tremendous progress in life sciences and technologies.

Human rights are not exempt of pluralistic interrogations, which even concern the most evident rights. Article 3 of the Universal Declaration on Human Rights (‘Everyone has a right to life, liberty and security of person’) is respected within the pluralism of national laws, when these include capital punishment or differently define the enormity of the crime for which a person may be deprived of life or liberty. This is not moral relativism, but ‘inherent flexibility’ as stated in a 1995 United Nations note on the challenge of human rights and cultural diversity(2): ‘Universal human rights do not impose one cultural standard, rather one legal standard of minimum protection necessary for human dignity. As a legal standard adopted through the United Nations, universal human rights represent the hard-won consensus of the international community, not the cultural imperialism of any particular region or set of traditions...Out of this process, universal human rights emerge with sufficient flexibility to respect and protect cultural diversity and integrity. The flexibility of human rights to be relevant to diverse cultures is facilitated by the establishment of minimum standards and the incorporation of cultural rights...Within this framework, States have maximum room for cultural variation without diluting or compromising the minimum standards of human rights established by law’.

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Universal principles of bioethics are often presented as four major obligations: 1) respect the autonomy in decision-making ability of the person and hence the obligation to obtain free informed consent; 2) beneficence in intention and action, e.g. therapeutic aim; 3) non-maleficence, above all no intentional harm and minimizing non-intentional harm; 4) justice and equality, treating everyone without discrimination. While already implied in these four principles, the obligation to respect human dignity and human rights is a foremost principle of bioethics which is emphasized expressly in the titles of the UNESCO’s Universal Declarations on the Human Genome and Human Rights, as well as on Bioethics and Human Rights.

Nevertheless, pluralism of culture and values, religious and philosophical perspectives, impacts and colours the principles of bioethics. Full autonomy, in some cultures, can be seen as limited by various considerations of collective good. Without violating the principle that ‘the interests and welfare of the individual should have priority over the sole interest of science or society’ (Article 3b, UDBHR), many would agree that confronted by a pandemic spread of disease, measures such as quarantine or obligatory mass vaccination may be needed, leading to inevitable limitations of freedom and autonomy. How far benefits (beneficence) for the collectivity, rather than solely for the individual, may be allowed to extend is still part of many debates, for example on the limits of genetic screening and selection, or internment of certain psychiatric patients. Refusing euthanasia asked by patients suffering in terminal diseases may be viewed as infringing on their autonomy. Offering certain drug treatments or surgery that entails high risks may conflict with non-maleficence. Plastic surgery to comply with societal fashion may sometimes raise questions about therapeutic aims. The bioethical principles of justice and equality are often subject to local economic variables, be it in capitalistic societies (inequity in health insurance; restricting treatments for old age, e.g. dialysis) or in developing countries (lack of means).

**Pluralism applied to bioethics at UNESCO**

The limits within which particular legal systems can be at variance without infringing on human rights are determined by international law. But for what concerns bioethical debates - in which cultural pluralism and human rights issues may be on the line - these are often of another nature, more subtle and complex because rooted in philosophical or religious outlooks on the human person, and because they revolve around moral and scientific definitions of humanity which are not in the realm of international law. The
two reports\(^{3}\) of UNESCO’s IBC for which a pluralistic approach has been specifically recommended are on the use of embryonic stem cells in therapeutic research and on preimplantation genetic diagnosis (PGD), topics that both affect embryos obtained by in vitro fertilization (IVF). Crucial issues revolve around definition of the beginning of human life: at what stage in its development does the fertilized egg, the embryo or the foetus become a person with human rights and what are these rights before pregnancy starts (e.g. IVF) or during pregnancy when its rights have to be related to the mother’s human rights (e.g. voluntary abortion). In addition, in view of the therapeutic and diagnostic medical relevance of these areas of scientific research, the human right ‘of everyone ... to enjoy the benefits of scientific progress and its applications’\(^{4}\) is a complementary principle which would be violated if these fields of scientific endeavour would be banned for all, solely on the basis of particular philosophical or religious doubts which are not shared by all in this pluralistic world. Similar considerations may be applied to other fields, for example therapeutic cloning\(^{5}\). Inasmuch as tissues derived from embryonic stem cell cultures could repair damages from neurological diseases or traumas, heart infarction or diabetes, and that the use of autologous embryonic stem cells produced by therapeutic cloning could prevent the rejection of the transplanted tissues, a pluralistic approach giving societies the right to decide whether or not to pursue the research, but in any case compelling them to set up ethical regulations, appears as the most appropriate course of action and this course was the one specifically adopted by UNESCO’s IBC in its report on the use of human embryonic stem cells in therapeutic research:

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4. International Covenant on Economic, Social and Cultural Rights, Article 15, UN 1966 (legally binding in 149 countries). Also Article 27 of the Universal Declaration on Human Rights, UN 1948: ‘Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancements and its benefits’.

5. On 8 March 2005, the UN General Assembly adopted resolution 59/280, containing in its annex the text of the United Nations Declaration on Human Cloning (a non-binding political declaration that would ‘prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life’) by a vote of 84 to 34, with 37 abstentions. The text had been adopted in the Sixth committee on February 18, 2005 by 71 countries in favor with 35 against and 43 abstentions.
1. It was decided that any report which the IBC might adopt on this matter should reflect this pluralism. This report, therefore, recognises that there are very marked differences of opinion relating to embryo research. It aims to highlight the various ethical arguments with a view to facilitating the resolution, at national and international level, of a controversial matter. It recognises that the solutions adopted by national ethical committees or national legislatures may well be different. Such differences are inevitable in a pluralistic world where people may sometimes adopt ethical positions which are unacceptable to others.

52-54 ... This issue has complex ramifications and the various views are obviously influenced by the concept of human life and personhood particular to each culture, religion or philosophy... Every society has the right and duty to debate and decide upon ethical issues with which it is confronted. Where there is fundamental disagreement, the society will have to decide where it stands on an issue either because the question involved relates to some fundamental value of that society or because practical considerations demand that the matter be resolved. The use of human embryos for deriving stem cells would appear to be one such issue. Human embryonic stem cell research – and embryo research in general – is a matter which each community (and this will usually mean a State) will have to decide itself. If the decision is reached after serious ethical debate, which allows for the expression of views in different directions, then this must be accepted if one believes in the principle of the democratic resolution of public issues. Examples of this process are afforded by IVF for fertility treatment and by pre-implantation diagnosis with embryo selection: there are differences of opinion on the ethical values involved and yet many States have decided that these medical practices are permissible.

55. ... The IBC recognises that human embryonic stem cell research is a subject on which it is desirable for a debate to occur at national level to identify which position on this issue is to be adopted, including abstaining from this research...Whatever form of research involving embryos is allowed, steps should be taken to ensure that such research be carried out within the framework of a State-sponsored regulatory system that would give due weight to ethical considerations, and set up appropriate guidelines...

The extensive emphasis on pluralism in this report, which further details religious and philosophical opinions, is an intrinsic component in the process of bioethical reflection and in its formulation of practical guidelines. Beyond the diversity of opinions on embryo status, the report establishes the ethical guidelines to follow if and wherever therapeutic research with embryos, left over after IVF, is permitted. Countries which do not allow extracting cells from IVF embryos, have on several occasions drawn from these guidelines
to import embryonic stem cells from other countries when they were convinced that the latter adhered to the ethical guidelines. This emphasis on pluralism is reiterated in the report on PGD. Once more, pluralism is not moral relativism, as Sir John Polkinghorne writes: ‘It is important to note that what is at issue here is not the force of universal moral principles, for all recognize the moral status of the human person. The differences arise from disagreement about how those principles are to be applied in this specific case, in particular what are the ‘facts’ about human personhood and the very early embryo...[there are] fundamental disagreements among people who are all genuinely seeking to act with ethical responsibility... [disagreements] located not on the surface of practical decisions, but in the profound depths of metaphysical theory about the character of humanity’(6).

Pluralism in opinions similarly prevails on questions related to the end of life. Realizing the irreversibility of scientifically defined brain-death, has made the donation and transplantation of vital organs a surgical procedure that saves daily many patients lives. If, as in some cultures, death is when respiration and heart beat ceases, saving one patient would never justify killing another person. The concept of a ‘life worth-living’, as in debates on euthanasia in terminal illness, is similarly touching ‘the profound depths of metaphysical theory about the character of humanity’. This concept may be encountered again in prenatal genetic testing, where bioethics supports the pluralistic principle leaving free the decision of the mother after informed and non-directive counselling(7). In such decisions, much depends on one’s views on body, mind and soul, on life’s potential versus biological (genetic) determination, on ‘the character of humanity’.

**The value of pluralism**

Pluralism is itself a value, a guaranty of coexistence and mutual understanding. But it requires definition and lucid boundaries. Such are proposed by Isaiah Berlin(8): ‘We are urged to look upon life as affording a plurality

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of values, equally genuine, equally ultimate, above all equally objective; incapable, therefore, of being ordered in a timeless hierarchy, or judged in term of someone absolute standard. These is a finite variety of values and attitudes, some of which one society, some another, have made their own, attitudes and values which members of societies may admire or condemn but can always...if they try hard enough, contrive to understand - that is, see to be intelligible ends of life for human beings...This doctrine is called pluralism’. Berlin states the limits in pluralism of values: ‘Incompatible these ends may be; but their variety cannot be unlimited...There is a limit beyond which we can no longer understand ...when the possibility of communication breaks down, we speak of derangement, of incomplete humanity. But within the limits of humanity, the variety of ends, finite though it is, can be extensive. The fact that the values of one culture may be incompatible with those of another, or that they are in conflict...does not entail relativism of values, only the notion of plurality of values not structured hierarchically ...

There is not one absolute standard, for all times and all human beings. No one has the whole or only truth: tolerance and the ability to say ‘I may be wrong’ as well as to see and understand the truth in the other’s opinion are central to the ethics of discussion, which is at the core of bioethics. Pluralism ought, therefore, to be part of bioethics in its task of prescribing how science may be applied for the good and welfare of the individual, as well as defining the limits of the permissible. However, the principles or ‘ends’ of bioethics should be like a building where harmonious assembly of complementary components is essential. These principles are diverse and encompass respect of human rights and dignity, respect for fundamental freedoms including being asked to give informed consent, receiving treatment with intent to heal (beneficence), with justice and without maleficence, respect for the right of everyone to benefit from the scientific advances, as well as respect for a cultural pluralism of values, even conflicting values that may concern the place of the individual in the collective, defining the beginning and end of life, or what makes up the quality of living. There are different ways to construct a harmonious building, but only a limited numbers of ways because if one principle is excluded or non-equilibrated, the construction will crumble. This is the limits of pluralism: no society can invoke its own cultural or political features, objectives or ends, to exclude one of the principles. Let us never forget that what the Nazi doctors did was to violate human dignity by discarding the very principles that are the essence of bioethics: they acted without consent, had no intention of beneficence for the person acted upon, acted with intent to harm, without justice and with discrimination on Jews and other inmates. This is the real danger.
A pluralistic bioethics is the opposite: it allows all to adhere and abide by the harmonious assembly of all the principles.

Bioethics is a continued process, new ethical reflections are needed continuously as science and technology progresses but, living in a pluralistic world, it is essential to ‘verify the validity of ... principles for the entire community of human beings’\(^9\). While being vigilant in the observation of human rights, one ought to have the wisdom not to add excessive precautions that would unnecessarily erect prohibitions, thereby negating other rights, duties and values and negating their promises for medicine and welfare. Pluralism is a value, provided there is mutual understanding which, in the final analysis, is to succeed making one’s good intentions intelligible and legitimate to all.

**Université et diversité culturelle dans la Déclaration universelle sur la bioéthique et les droits de l’homme**

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**Résumé**

La recherche d’un équilibre entre l’universalisme de certains principes relatifs à la bioéthique et le respect de la diversité culturelle a été l’une des préoccupations principales des rédacteurs de la Déclaration universelle sur la bioéthique et les droits de l’homme. C’est une des raisons pour lesquelles le nouvel instrument ne cherche pas à donner une réponse détaillée à toutes les questions de bioéthique. Au contraire, il se limite à refléter le consensus international autour de certains principes de base qui constituent le seuil minimal de ce qu’exige le respect de la dignité humaine dans ce domaine. Autrement dit, la Déclaration ne vise pas à réduire la diversité des traditions socioculturelles et des systèmes juridiques, mais à établir un cadre de principes généraux en vue de promouvoir le respect des droits de l’homme en matière biomédicale.

**Abstract**

The search for a balance between the universalism of some bioethical principles and the respect for cultural diversity was one of the major concerns of the drafters of the Universal Declaration on Bioethics and Human Rights. This is one of the reasons why the new instrument does not intend to provide a detailed answer to all bioethical dilemmas. On the contrary, it only aims to reflect the international consensus on the minimum standards required to ensure the respect for human dignity in this field. In other words, the Declaration does not pretend to reduce the diversity of the various
sociocultural traditions and legal systems, but to establish a framework of general principles in order to promote the respect for human rights in the biomedical field.

Introduction

Je voudrais centrer mon exposé sur l’équilibre entre universalisme et respect de la diversité culturelle dans la Déclaration universelle sur la bioéthique et les droits de l’homme, adoptée le 19 octobre 2005, ainsi que sur le rôle décisif que jouent les droits de l’homme dans cet instrument.

La grande question ici est à mon avis la suivante : Est-il possible, dans un domaine aussi sensible que celui de la bioéthique, d’élaborer des normes à validité universelle ? Autrement dit, peut-on en bioéthique concilier l’aspiration à l’universalité avec le respect de la diversité culturelle ? Celle-ci est une des questions qui a été au cœur des travaux d’élaboration de la nouvelle Déclaration.

Cela s’explique bien. La bioéthique est en effet un domaine particulièrement sensible. Elle est liée à des valeurs qui sont parmi les plus précieuses pour toute société humaine : la vie humaine, l’intégrité physique des personnes, le respect du corps. La bioéthique nous renvoie, d’une manière ou d’une autre, à des traditions culturelles, juridiques, philosophiques et religieuses qui sont forcément différentes. C’est pourquoi, dans une première approche, on serait tenté de dire que l’élaboration de normes à validité universelle sur la bioéthique est une tâche impossible.

Cependant, lorsqu’on examine de plus près ce défi, on parvient à la conclusion contraire. Justement parce que la bioéthique est liée à ce qu’il y a de plus intime dans l’être humain, et puisque l’être humain est le même en Guinée qu’en France, en France qu’au Japon, au Japon qu’au Canada, il est bien possible de trouver des points de repères communs. Cela, à condition, bien sûr, qu’on se borne à formuler des principes suffisamment généraux pour permettre à la fois de parvenir à un consensus universel et de respecter les spécificités culturelles de chaque société.

C’est justement ce que la nouvelle Déclaration fait. Elle ne prétend aucunement dresser une liste exhaustive et détaillée des normes relatives à la bioéthique. Bien au contraire, elle se limite à énoncer des principes très généraux en les concevant comme une sorte de socle commun à toutes les sociétés humaines.
I. La diversité culturelle et la bioéthique

Le souci du respect de la diversité culturelle a été exprimé à plusieurs reprises lors des travaux d’élaboration de la nouvelle Déclaration, tant en général qu’à propos de chaque sujet de bioéthique en particulier. L’importance de la question avait été déjà soulignée dans le Rapport du CIB sur la possibilité d’élaborer un instrument universel sur la bioéthique, finalisé le 13 juin 2003. Ce document, dont les rapporteurs ont été les Professeurs Berlinguer d’Italie, et De Castro des Philippines, affirme :

Quand nous nous efforçons d’établir des principes éthiques universels, il nous faut admettre l’existence de nombreuses formes différentes d’éthique en général et de bioéthique en particulier. Cet état de choses doit être considéré comme une manifestation de la liberté humaine plutôt que comme un obstacle. Dès lors qu’il n’entre pas en conflit avec les droits des personnes présentes et à venir, le pluralisme bioéthique devrait être non seulement permis mais reconnu. Simultanément, l’instrument universel devrait chercher à stimuler l’élaboration d’un sens commun universel (a universal common sense), afin de favoriser la compréhension et la cohésion autour des nouvelles catégories éthiques et des nouvelles possibilités offertes par la science et les technologies.\(^1\)

De même, il est important de rappeler que la diversité culturelle est au centre des préoccupations de l’UNESCO depuis sa création. L’Acte constitutif lui-même de l’UNESCO signale parmi les objectifs de l’Organisation celui d’« assurer aux États membres l’indépendance, l’intégrité et la féconde diversité de leurs cultures »\(^2\). C’est justement en réalisant cet objectif que l’organisation a été à l’origine de la Déclaration universelle sur la diversité culturelle, adoptée en 2001, ainsi que de la Convention sur la protection et la promotion de la diversité des expressions culturelles qui vient d’être adoptée. C’est dans ce même cadre de respect de la diversité culturelle que l’UNESCO connaît bien, que s’inscrit la nouvelle initiative de l’Organisation dans le domaine de la bioéthique.

Il est intéressant de remarquer que le Préambule de la Déclaration universelle sur la bioéthique et les droits de l’homme cite parmi ses sources la Déclaration universelle sur la diversité culturelle de 2001. Ce dernier texte nous rappelle que la diversité culturelle est une « source d’échanges, d’innovation et de créativité » ; loin d’être un obstacle, elle constitue une

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2. Acte constitutif de l’UNESCO (1945), art. 1, al. 3.
richesse pour l'humanité ; elle est aussi nécessaire à l'humanité que l'est la biodiversité dans l'ordre du vivant. En ce sens, « elle constitue le patrimoine commun de l’humanité »(3).

La nouvelle Déclaration sur la bioéthique contient une norme spécifique à propos de cette question, l'article 12, intitulé « Respect de la diversité culturelle et du pluralisme ». D'après ce texte :

Il devrait être tenu dûment compte de l’importance de la diversité culturelle et du pluralisme. Toutefois, ces considérations ne doivent pas être invoquées pour porter atteinte à la dignité humaine, aux droits de l’homme et aux libertés fondamentales ou aux principes énoncés dans la présente Déclaration, ni pour en limiter la portée.

Cet article, qui à première vue pourrait paraître trop vague ou imprécis, est en fait d’une portée énorme.

La première phrase, qui pose le principe de respect de la diversité culturelle, est forcément générale car il est impossible dans un texte de cette nature de rentrer dans le détail de ce que signifie ce respect à propos de chaque pratique biomédicale. Cependant, cette affirmation est importante parce qu’elle attire l’attention sur le fait que la diversité culturelle est à respecter aussi dans le domaine de la bioéthique.

La deuxième phrase de l’article 12 est aussi d’une grande portée. Elle vise à signaler que le principe de respect de la diversité culturelle n’est pas absolu, mais qu’il s’inscrit dans le cadre du respect des droits de l’homme. Cela veut dire qu’on ne peut pas invoquer la diversité des traditions socioculturelles ou religieuses comme alibi pour justifier des pratiques qui sont contraires à la dignité humaine et aux droits de l’homme. Il faut admettre, en effet, qu’il y a des exigences de justice à l’égard de tout être humain, quelle que soit la culture à laquelle il appartient et où qu’il habite. Ce respect se traduit en matière biomédicale par des principes de base qui ont par conséquent une validité universelle. Ainsi, juste à titre d’exemple, on peut affirmer que personne ne doit être soumis à des interventions biomédicales sans son consentement ; que personne ne doit être discriminé ou stigmatisé pour des raisons de santé ; que les pratiques cliniques doivent chercher le bien du patient et, avant tout, à ne pas lui nuire (primum non nocere) ; que personne ne doit subir la divulgation d’informations confidentielles le concernant ; que ceux qui sont plus vulnérables méritent une attention majeure, etc. En fait, une bonne partie de la nouvelle Déclaration contient des nor-

mes qui prennent en considération un aspect particulier du respect que l’on doit à tout être humain en matière biomédicale.

2. Les droits de l’homme comme cadre de la bioéthique internationale

Je pense donc ne pas me tromper en disant que la nouvelle Déclaration conçoit ses principes comme une sorte de prolongement des normes sur les droits de l’homme dans le domaine spécifique de la biomédecine.

Pourquoi ce recours aux droits de l’homme?

Tout d’abord, il y a le fait incontournable que les activités biomédicales touchent à une dimension essentielle de la personne : sa vie, sa santé et son intégrité physique et psychique. Il est donc normal qu’en vue de protéger ces valeurs, on ait recours à l’instrument juridique le plus mobilisateur de l’action politique dont on dispose : celui des « droits »(4).

Une autre raison, plus pragmatique, est que la structure conceptuelle des droits de l’homme facilite la formulation de normes à validité universelle. Il convient de rappeler que les droits de l’homme sont normalement conçus comme des prérogatives fondamentales de la personne humaine qui transcendent la diversité des cultures. Ce sont des droits qui correspondent à l’être humain en vertu de sa seule condition humaine. Pour employer les mots de Paul Ricoëur, ces droits s’appuient sur l’idée que « quelque chose est dû à l’être humain du seul fait qu’il est humain »(5). Tous les êtres humains ont donc « des droits égaux et inaliénables », car tous participent à la « dignité inhérente à tous les membres de la famille humaine »(6). C’est ce qu’on appelle l’universalité des droits de l’homme. Cette universalité est une caractéristique essentielle des droits fondamentaux de la personne. En fait, on ne pourrait même pas penser à eux s’ils n’étaient pas universels car, comme le souligne avec force l’Ambassadeur Gros Espiell, « les droits de l’homme sont universels … ou il ne sont pas »(7).


6. Cf. Déclaration universelle des droits de l’homme de 1948 (Préambule) ; Pacte international relatif aux droits civils et politiques de 1966 (Préambule) ; Pacte international relatif aux droits économiques, sociaux et culturels de 1966 (Préambule).

C’est donc surtout cette universalité qui explique la tendance actuelle à inscrire les normes internationales sur la bioéthique dans le cadre des droits de l’homme. Cette tendance est relativement récente. La Déclaration universelle sur le génome humain et les droits de l’homme de 1997 a d’une certaine manière ouvert la voie dans cette direction au niveau international. La Convention sur les droits de l’homme et la biomédecine du Conseil de l’Europe en a fait de même au niveau européen. La nouvelle Déclaration, qui s’intitule sur la bioéthique et les droits de l’homme, s’inscrit aussi nettement dans cette même démarche. Ainsi que le souligne la Note explicative sur l’élaboration de ce texte, « le groupe de rédaction a (...) insisté sur la nécessité de prendre le droit international des droits de l’homme comme cadre et base de départ essentiels pour l’élaboration des principes bioéthiques »(8). D’après ce document, il y aurait deux grands courants qui sont à la source de la bioéthique : l’un, qui remonte à l’antiquité et notamment à Hippocrate, est le produit de réflexions sur la pratique de la médecine ; l’autre, plus récent, s’appuie sur le développement du droit international des droits de l’homme. Et il ajoute : « l’un des acquis les plus importants de cette déclaration, c’est qu’elle cherche à unir ces deux courants. Elle vise clairement à mettre la bioéthique en conformité avec le droit international des droits de l’homme »(9).

**Conclusion**

Enfin, pour conclure, je dirais que la recherche d’un équilibre entre l’universalisme de certains principes relatifs à la bioéthique et le respect de la diversité culturelle a été l’une des préoccupations principales des rédacteurs de la Déclaration universelle sur la bioéthique et les droits de l’homme. C’est pourquoi cet instrument ne cherche pas à donner une réponse détaillée à toutes les questions de bioéthique. Au contraire, il se limite à refléter le consensus international autour de certains principes de base qui constituent le seuil minimal de ce qu’exige le respect de la dignité humaine dans ce domaine. Autrement dit, la Déclaration ne vise pas à réduire la diversité des traditions socioculturelles et des systèmes juridiques, mais à établir un cadre de principes généraux en vue de promouvoir le respect des droits de l’homme en matière biomédicale.

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SESSION III
“INFORMED CONSENT”

- Mrs (Prof.) Sheila McLean (United Kingdom)
- Mr (Prof.) Eugenijus Gefenas (Lithuania)
- Mrs (Prof.) Regine Kollek (Germany)
- Mrs (Prof.) Heloisa Gonçalves dos Santos (Portugal)
- Mr (Dr) Tadafumi Kato (Japan)
IS CONSENT ALWAYS THE APPROPRIATE CONCEPT?

Mrs (Prof.) Sheila McLean,
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Firstly I wish to thank UNESCO for the invitation to be here today and to Sophia University for hosting this very interesting conference.

It is perhaps a little unfortunate that I am the first speaker this afternoon because I would like to suggest that there are in fact some limitations to the concept of consent which require further consideration. So rather than simply endorsing consent I want to look at one particular set of circumstances which I think poses some interesting questions, some of which the Chairperson has already referred to.

Obviously I do not deny the importance of consent, since it respects and reinforces important values like peoples’ right to autonomy and of course it mandates the ethics and integrity of clinical interventions. However, I would like to suggest that consent has a third function and when we look at this particular function, we are forced to conclude that there may be some problems raised by it which are not easily met by the traditional interpretation of consent in law. This third function is essentially to locate authority in proxy decision-makers, such as parents, but it may be limited by the traditional interpretation of consent.

My interest in this area was raised by two distinct incidents in the last forty years. As the Chairperson rightly said, recent interest in consent was triggered by the Nuremberg trials and its importance has permeated medical law and bioethics ever since. The two incidents which I will focus on, however, arose more recently, and specifically concern the appropriate authority to be granted to parents called upon to make decisions about what may or may not be done in respect of their deceased children.
It came to light in the last five years that, in a number of countries throughout the world, perhaps most acutely in the United Kingdom but also in Australia and elsewhere, the organs of deceased children had been removed and retained for a variety of purposes and in some cases for no apparent purpose that anybody could discern, without the consent of the parents to the removal or retention of the organs. When this came to light, unsurprisingly it caused considerable concern, resulting in the setting up of three committees of inquiry in the United Kingdom, one of which I chaired. Even before these events were taking place, a further project had been carried out in the United Kingdom, which also involved the use of body parts from deceased individuals – in this case, their bones.

This project was known as ‘Operation Sunshine’, and was initiated by the United States, although it was conducted in collaboration with international scientists, with much of the research being carried out in the United Kingdom. A substantial amount of it was carried out in Glasgow where I happen to live - partly because of available expertise and partly because of geography. This project essentially involved the removal of bones from dead children (mostly) but occasionally dead adults, again without anyone having been informed of this and without any form of agreement having been reached with their loved ones. The intention of the project was to identify the impact of the explosion of so-called ‘dirty’ nuclear bombs (this was during the cold war) by evaluating the extent to which Strontium 90 was absorbed by people geographically close to where the bombs had been detonated. Bone could be analysed, and it was possible to identify the rate of absorption of Strontium 90 and the extent to which it lasted throughout a person’s life.

In the other examples, although some doctors intended to – and did – carry out possibly beneficial research on the organs and tissue which were retained, the focus of the parents’ concerns was on the fact that they had not been asked to give their consent to this, nor had they even been informed. Unsurprisingly, all the families concerned in each of these events felt themselves to have been harmed or wronged by the fact that they had not been invited to agree to the use of their children’s bodies in this way. Given the commitment of countries like the United States, Australia and the United Kingdom to the importance of consent, it is perhaps paradoxical that these incidents arose in just these countries, or were initiated by them. Even if the importance of the projects were clear - and they certainly were in the Strontium 90 example used, which led to recognition of the value of breast feeding as well as making a contribution to the nuclear non-proliferation treaties which followed the cold war – for the families concerned they showed a lack of respect for their special
place in the lives of their family, particularly their children, and represented an ethical and a legal wrong.

I fully appreciate that different countries and cultures may take different approaches to who is an appropriate decision-maker in circumstances of this sort. While in some countries, or cultures, the appropriate decision-makers might have been the entire community, in others – like the United Kingdom – the appropriate decision-maker in the case of children is either the parent(s) or someone else who is in loco parentis. In the case of adults, the situation is more complex, legally speaking, so I will for the moment and in the brief time available, confine my comments to the relationship between parents and children.

The question I want to ask is whether or not – as the law is presently understood - there was in fact a legal as opposed to an ethical harm caused to them. That is, whether or not the notion of consent could in fact have addressed the situation in which they found themselves. In most countries, irrespective of who is the ultimate decision-maker, where the person who is the subject of any consent process is incompetent – as is obviously the case with very young children – the assumption is that parents can make medical decisions on their behalf. But these decisions must be made in the ‘best interests’ of the child. There is of course an argument that we should see a dead body as being a community resource, rather than as an entity within the sole authority of parents, but by and large this is not the approach adopted. Rather, we maintain the respect that we would have for them in life even following their death, thereby placing limitations on what can and cannot be done with or to them.

That means that those who have the legal authority to authorize procedures in their respect have to do so within the constraints to which I have already referred; that is, decisions should follow appropriate information disclosure and should be in the ‘best interests’ of the person in whose respect the consent is sought. However, the question must be whether or not it can ever be in the best interests of a deceased child to have a post mortem examination conducted on them. The answer would seem to be in the negative. That being the case, it can also never be in their best interests that diagnostic, therapeutic, research or educational interventions are carried out on their body or body parts. If so, then the rights that parents otherwise have to make decisions are not appropriate here.

The problem with that conclusion is, of course, significant. In the case of the removal and the retention of organs there was – in most if not many cases – some good therapeutic, diagnostic, research and educational work done with the organs that had been removed. So there was a potential social benefit. Indeed, in the specific case of the Strontium 90 research, considerable benefits
accrued from it. However, even this would not justify in law (nor in ethics) the failure to seek authority for the use of body parts. In fact, on my argument, not only was nobody with a relationship to the deceased asked for their consent, arguably they would have been unable to provide a legally binding consent even if they had been asked, because of the requirement that they can act only in the best interests of the child. This would be an unfortunate conclusion, as it would presumably prevent any and all post mortem examinations and much medical research.

If consent is given its usual meaning, two consequences would follow. First, that parents would need to be given adequate information about the uses to which their children’s bodies would be put; and, second, that they would very possibly not have the legal authority to consent in any case. So, even if information had been provided, it may not have legitimised parental consent. A way forward needs to be found. The Inquiry in Scotland which I chaired took this problem seriously, and proposed an alternative concept, which in cases of this sort would replace the traditional concept of consent. This concept was ‘authorisation’. The premise here is that authorisation is a better and more appropriate concept than consent for the following reasons. First, that is locates the power of decisions firmly where they should be – in this case, with the parents. Second, given that authorisation is not dependent on information disclosure, parents who wish not to receive information about what will be done with their children, can nonetheless act altruistically to allow their child’s death to help others, for example by agreeing to medical research. Finally, ‘authorisation’ is not constrained by the ‘best interests’ requirement, given that it hands over clear authority to parents.

I am pleased to say that the Scottish Parliament has taken this particular argument on board, and the Human Tissue (Scotland) Act 2006 replaces the concept of consent with that of authorisation, both in removal and retention of organs for diagnostic, research or educational reasons, as well as in the case of organ transplantation. Although we may still instinctively believe that there are no differences between consent and authorisation, I believe that there are and these are referred to above. We may be comfortable and familiar with the language of consent, and although we accept and respect the good that it can do in protecting people, it is not only a relevant concept. Indeed, sometimes it may prevent a good outcome, because of the careful way in which it has been interpreted in law over the years. If my conclusions are correct, we may also have to revisit not just domestic law, but also international agreements, for example the Declaration of Helsinki, to take account of the conceptual differences between consent and authorisation where research or other activities are not designed to help the child.
INFORMED CONSENT: IMPLEMENTATION CHALLENGES

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Informed consent is one of the fundamental issues in bioethics. First of all, it has marked the emergence of modern health care ethics and has transformed a traditional health care provider-patient relationship. The shift from traditional paternalism to personal autonomy-oriented health care has already been one of the major bioethical issues in Western Europe and North America for a few decades. Developing countries appreciate the importance of informed consent as soon as human rights movement and democratic developments become a sufficiently prominent feature of the society’s life. For example, in most of the countries of Central and Eastern Europe the controversy between personal autonomy and paternalism as well as the importance of informed consent for different health care contexts have been in the centre of the bioethical debate since the late eighties.

Nowadays the principle of informed consent has become a well-recognized legal and ethical requirement. It has been widely accepted in both clinical practice and biomedical research. For example, legalizing informed consent has provided rather clear guidelines for many clinical situations and has probably been the most powerful factor transforming doctor-patient relationship almost all over the world during the last decades. More or less clear and strict standards have also been developed in such areas as biomedical research, organ transplantation, not to mention ordinary health care related interactions between a doctor and a patient.

In the field of biomedical research informed consent has been one of the key principles incorporated into the international guidelines that were supposed to be followed in different countries and continents of the world.
The Declaration of Helsinki, the Council of Europe Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, International Ethical Guidelines for Biomedical Research Involving Human Subjects prepared by CIOMS – these are but a few examples of international instruments that all list informed consent as one of the key principles of biomedical research.

The Universal Declaration on Bioethics and Human Rights adopted by the General Conference of UNESCO in October 2005, extends the application of the principle of informed consent as well as makes a broader emphasis on personal autonomy both in the field of biomedical research as well as clinical practice. What is also of paramount importance – the Declaration extents the geography of the principle of informed consent as it becomes a universally accepted principle all over the world.

However, even if the principle of informed consent is one of the most often discussed and elaborated issues in bioethics, its implementation poses difficulties still to be faced. The most general one is related to the dilemmatic character of the bioethical discourse itself, namely, the necessity to balance the contradicting values and worldviews related to health care choices. It should be pointed out that the complexity of human life does not allow to base health care on a single paradigm of legal and ethical principles, would it be a personal autonomy or patient’s well-being. The principle of personal autonomy has its own limitations, which are especially visible when a doctor has an encounter with a vulnerable and suffering person. For example, despite the requirement to provide information to the patient about his or her diagnosis and prognosis, there are some important circumstances when such a provision cannot be implemented because there are cases when this might not be in the patient’s best interests: a patient might not be able to cope with certain information, for example a very poor prognosis. How should a doctor decide what information can be conveyed in such a case to the patient?

These questions are even more important if we think about different socio-cultural contexts where the principle is supposed to be applied. Not all the societies assign an equal value to individual autonomy even in the European context. In addition, the shift from paternalism to autonomy cannot be achieved by a simple change of legislation. Both health care practitioners as well as their patients have to change their attitudes towards the responsibility to carry the burden of the knowledge related to illness and disease to make the implementation of the principle meaningful. It is also important to note that the implementation of the informed consent should be followed by the transformation of other related aspects of health care pro-
vider – patient relationship, such as respect for privacy and confidentiality. These problems might be even more difficult in the countries where strong community-oriented values should be balanced with the attempts to respect the choice and autonomy of the individual.

Implementation of the principle of informed consent in the field of biomedical research is no less complex and difficult even if the requirement to follow it in this field is much stricter and more universally accepted. First, as has been shown by many empirical studies, so-called ‘therapeutic misconception’ is still a very widely spread phenomenon even in the developed industrialized societies where pharmaceutical clinical trials have been conducted for many years. Still too many research participants do not understand the meaning of placebo controlled blind clinical trials they are participating in. For example, according to the study conducted in Lithuania a few years ago, the fact that some of the participants in the placebo controlled double blind clinical trials receive a new drug while others receive a substance without any pharmaceutical activity (a placebo) was understood by only one-third of the research participants. Finally, the question ‘Do you think your doctor has been aware of what exactly is being administered to you?’ was answered positively by almost 40% of participants, who evidently misunderstood the double-blind character of the trial (1).

Let us also consider the problem of consent to phase I oncology trials. It has been demonstrated by empirical studies on informed consent that only 33% of the research participants clearly understood that the main purpose of such a trial is to help future patients rather than hope for his or her own benefit; similarly, only 30% acknowledged the no-treatment-except-for-palliation option that was discussed as an alternative to participation in the information sheet provided to the patients (2).

Still another problem is related to the difficulties to follow the principle of informed consent in the large scale studies that are supposed to bring only ‘minimal risk’ for the potential research participants. For example, population based genome projects reveal more systematic difficulties in conforming to the standards of informed consent applied in traditional clinical trials and might therefore also prompt us to think about alternative research ethics paradigms (3). Some bioethics experts would argue that it might not always be feasible to obtain informed consent, even from individuals who are competent to give it and understand the issues, because it is not possible to foresee the full range of uses to which genetic information might be put. According to the proponents of this point of view, the strict requirement of informed consent evolved as a reaction to Nazi experiments, whereas the
context has changed in contemporary research. An alternative of so-called ‘open consent’ has been proposed to facilitate these types of research.

These are some of the examples that show the importance and difficulties in implementing the principle of informed consent in the clinical practice as well as biomedical research. To summarize, the most important challenges to implement the principle of informed consent stem from what we might call socio-cultural ‘resistance’ to the change. First of all, time is needed to implement new normative requirements and a legal reform is just the first step in this complex process of changing different normative perspectives. In order to facilitate this change, empirical studies might be a very useful tool to monitor the situation and to develop effective policy making strategies. However, it should also be kept in mind that health care decision making cannot be based on a single moral paradigm, which is also the reason why health care choices will always be characterized by their dilemmatic character.

The mentioned problems suggest that different application strategies of the principle of informed consent sensitive to the socio-cultural background and new scientific developments should be developed. The IBC could take the initiative to engage in this important activity.

References:
INFORMED CONSENT

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Abstract

Clinical research on human beings should only be carried out with the prior, free and informed consent of the person concerned. This doctrine originates in the nineteenth century, when scientific and experimental methodology was introduced into clinical medicine. It is also a reaction to the horrible experiments on human beings carried out by German doctors during the 1930s and 1940s, and to reprehensible studies on unsuspecting patients in the United States of America after World War II. First codified in Prussia in 1900, the moral duty of physicians and researchers to obtain consent became more widely recognized after the publication of the Nuremberg Code in 1947, and lastly after the adoption of the Ethical Principles for Medical Research Involving Human Subjects by the General Assembly of the World Medical Association, Helsinki in 1964. The necessity to obtain informed consent for medical research on human subjects sets limits on the ability of the State, of medicine and the community to govern individuals. It therefore represents a fundamental ethical and legal requirements that protects the patients and their rights of personal autonomy and bodily self-determination.

Although informed consent has been widely accepted in ethical discourse, its application in medical practice is neither easy, nor without contradictions; hence it is confronted with various challenges. They can partially be accounted to the fact that consent is understood differently by various disciplines and professions and in various theoretical models. However, these challenges also originate in the specificities of the local circumstances
and cultural contexts in which informed consent is applied. For example, it is not always clear, what counts as an informed decision, and what kind of information must be given to patients or subjects asked to participate in research. Furthermore, under certain circumstances, scientific design of clinical trials may require to withhold specific information from research subjects in order not to tamper results. Another question may be, whether the gradual extension of informed consent may lead to situations where the physician’s exercise of judgement is marginalized to the detriment of the patient. Further challenges are posed by the fact that the doctrine of informed consent is culturally bound. It is – like medical science and technology and the ethics designed to deal with its impact – very much shaped by liberal individualism that has its roots in western culture. Because of its adherence to an individualistic perception of the person it may create problems when applied in other cultural contexts. For example, in western culture, the individual is the locus of decisional capacity and informed consent. However, this concept may become problematic or even meaningless in societies that stress the overriding importance of an individual’s relationship to family and community.

These and other challenges have to be met if we want to promote a fruitful debate on standards on informed decision making, which are universally applicable on the one hand, but sensible to the requirements of local and cultural contexts on the other. In my presentation, I will first depict some of the challenges posed by the differences between the contexts of application of informed consent. Secondly, I will identify tasks for international discourse on informed consent that arise from this situation, and thirdly I will reflect on the question whether different application strategies of the doctrine of informed consent are needed, and how they could be designed.
INFORMED CONSENT

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Introduction

Promoting freedom of choice by improving the conditions of consent in the preventive, diagnostic and therapeutic medical interventions is one important consequence of respecting traditional ethical principles in medicine and biomedical research – autonomy, beneficence, non-maleficence and justice – namely, of course, the principle of autonomy and self-determination, but also the principle of beneficence and non-maleficence.

Informed consent is obviously closely linked with the principle of human dignity and human rights. As you know, the importance of free consent was really better understood after World War II when humanity discovered the astonishingly coercive, criminal medical research carried out during the Nazi years. As a consequence of this, the principle of free consent in research was introduced in the so-called, Nuremberg Code.

Today the two main reasons for the difficulties in obtaining full acceptance of this essential principle are the traditional paternalistic attitudes in medical practice, assumed by some physicians and accepted by most patients justified as promoting patient welfare, and also the different cultural values and practices in the populations.

Furthermore, nowadays it will be necessary for professionals working in pluralistic societies to be aware of the differences and be prepared for obtaining the freedom of choice in an adequate manner, respecting both cultural traditions and ethical principles.

Nevertheless it will also be necessary to bear in mind that the importance of informing and respecting the patient’s choice is one essential goal in
our modern world characterized by a faster – sometimes too fast – growing of science and technology and increasing demands of commercial competition.

And, of course, in our global world, the informed consent should be offered not only in common medical practice, but also in special different choices related to the new technical and scientific challenges such as human transplants, reproductive medicine, related developments to the human genome and biomedical research including drug assays.

**Conditions of informed consent included in the Universal Declaration on Bioethics and Human Rights**

**Adequate information**

The information should be given respectively by the health-care professionals or by the responsible researchers (after the research is approved by an ethics committee).

Information shall be complete and cover risks and benefits, and in so far as it is possible, should be unbiased and should offer different alternatives.

The time dedicated to providing information must give patients a full opportunity to ask all their questions concerned with their consent. If necessary it must be repeated to give more details to the patients or family.

With respect to genetic problems – such as prenatal diagnosis or predictive testing - it will always be necessary to give more complex information and offer genetic counselling. Under these conditions the patient’s decision must be received within a few days (such as in prenatal diagnosis) or even months later (such as in predictive genetic testing).

**‘Appropriate’ consent**

The appropriate consent’s characteristics and the level of detail are obviously not the same under different conditions. If we compare the common medical therapeutics, the surgical therapeutics, participation in scientific research or carrying out predictive genetic testing in healthy people, we agree that it is necessary to offer different forms of consent. Express and free consent can be verbal or documented in written form.

In the first case of common medical therapeutics, it can be considered an acceptable ethical procedure to obtain a verbal free consent after the medical practitioner has given the patient adequate information.
In the three remaining cases (of) surgical therapeutics, scientific research and predictive genetic testing – the procedures cannot be carried out without an express and documented consent that should be written except in specific exceptional circumstances, namely illiteracy.

It is advisable – and mandatory in scientific medical research – that the written consent form must include the main purpose, nature, consequences and risks of the intervention but, of course, these explanations can never replace the prior adequate and essential verbal information.

In addition it is absolutely necessary to give full information – verbal and/or written - about the total acceptance of the withdrawal of consent without any future consequences for the persons involved.

With a few exceptions, it is not acceptable to obtain a written form signed by a person with illiteracy. This signature doesn’t mean that this person was previously informed or influenced or even forced to sign. It is perhaps better to have the signature of a friend, or a close member of the family obviously chosen by the patient, confirming the informed verbal consent.

It is necessary to emphasize that even accepting different traditional and cultural standards, the goal of informed consent is to protect self-determination and choices of the autonomous person. According to this goal, it is not acceptable to transfer the agreement to other persons including other members of the family, legal representatives or community leaders. However an additional agreement could perhaps be accepted but only in a few conditions mainly related to research.

**Persons without the capacity to consent**

Autonomous persons are protected by informed consent and we have previously established the most important ethical and technical requirements governing this practice. However, it will also be necessary to guarantee the protection of persons not able to consent or not consenting with full capacity. In all situations the two most important general values to keep in mind are the protection of the best interests of the persons concerned and the total respect for the personal decisions expressed, including refusal.

Different groups of adults with permanent incapacity of self-determination (mental retardation, Down syndrome, dementias, etc.) to other groups with transitory incapacity (coma, Intensive care, children, etc.) should have different guidelines and restrictions and the requirements should be different whether it is used for research or medical practice and whether it is used for healthy or sick people.

Research and medical practice in children and the best conditions of offering informed consent are an important and difficult matter but all
must be done only in their best interest. The importance of knowing and respecting the position of the minor when older and able to express his position must always be necessary. Genetic testing of healthy children without the possibility of adequate treatment during childhood, even considering parents’ rights, should not be accepted mainly because the children lose the opportunity to make their own decisions later as autonomous adults. In addition to this confidentiality would be forever lost as well as their self-esteem and they run the risk of social and familial stigmatization.

So, in conclusion, informed consent is an essential ethical principle in medicine and biomedical research closely linked with human rights that needs to be properly offered and accepted by different cultures and populations. More well-defined guidelines must be established to ensure its appropriate and sometimes very difficult application.
INFORMED CONSENT: CURRENT STATUS
IN CLINICAL AND RESEARCH SETTINGS IN JAPAN

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Introduction

As a Japanese psychiatrist working primarily in clinical research, including neuroimaging and molecular genetics, Kato will discuss:
1) Acceptance of informed consent (IC) in Japan;
2) Problems surrounding IC in psychiatry;
3) Current problems associated with IC in clinical research.

Informed consent in Japan

The term ‘informed consent’ is difficult to translate into Japanese because of inherent linguistic differences. Setsumei-Doui was the original translation, which means: inform and consent, but the relationship between ‘inform’ and ‘consent’, as well as who is informed and who is consented, are vague and therefore hampered proper understanding of this concept initially. Now, the term ‘informed consent’ is used without translation as Japanese loanword (a word taken from another language). However, the use of the English term itself suggested that IC itself was a difficult concept to understand and created a different barrier to comprehension, especially for elderly people. The committee for the National Institute for Japanese Language, which has repeatedly expressed concerns over the excessive use of loanwords in Japan, proposed using Nattoku Shinryō that can be translated as ‘satisfied medical treatment’ in 2002. However the application of this term is far narrower than ‘informed consent’, which can be applied more generally to other aspects of daily life than medical care. As a result,
their term failed to attract public acceptance. The term ‘informed consent’ remains widely used in Japan and is gaining wider, if limited, recognition.

IC became popular following the Nürnberg trials (1945-6) that judged the crimes committed against humanity by the Nazis. A PubMed database search of medical and scientific papers shows that the first paper to use the term ‘informed consent’ appeared in 1951 followed by a rapid increase in use in early ‘70s that may have been facilitated by the Declaration of Helsinki of 1964 that required informed consent from all subjects participating in clinical research.

By contrast, the same literature search using Japana Centra Revuo Medicina, indicates that ‘informed consent’ in Japan first appeared in 1996 as a keyword. In 1999 the number of papers using this keyword abruptly increased probably in response to a revision in Japan’s medical laws that make reference to informed consent.

These results indicate that researchers and clinicians did not voluntarily adopt the concept of informed consent. It was imposed on them through governmental regulations. Why were Japanese researchers and clinicians reluctant to incorporate IC into their practices until required by law? In Japan, where the doctor-patient relationship is predominantly paternalistic, cultural factors seem likely. The Chinese philosopher, Confucius, best demonstrates this attitude when he wrote that ‘the leader can establish a relationship of mutual trust. But, it is difficult to inform everything to the public.’ Furthermore, in contrast to United States, Japan has fewer medical lawsuits reflecting the tendency of the Japanese people to public interests over their own.

**Informed consent in psychiatry**

Most ethical problems are more clearly and strongly evident in psychiatry. What is the patient-doctor relationship? What is free will? Whose right should be protected? Thus, IC entered discussion of psychiatric practice earlier than it did into others. In fact, that 1951 scientific paper found in PubMed discussed the necessity of informed consent in electroconvulsive therapy (ECT) for patients with mental disorders (Paytel, 1951).

ECT is the most effective and rapid treatment for severe depression. However, severe side-effects, including accidental death and life-threatening cardiac problems in 1 of 500 cases, as well as temporary memory disturbances, although rare, can be experienced.

Based on data showing that psychosis and epilepsy rarely coexist in patients, inducing seizures in patients with psychosis using chemicals was
proposed as a treatment option in 1935. Electro-Convulsive Therapy (ECT) evolved from this idea in 1938. Several years later, to ameliorate side effects and to soften the harsh treatment environment, anesthesia and neuromuscular blockades were included in ECT. This treatment is called modified ECT or mECT. With the emergence of psychotropic drugs in the 1960s, use of ECT declined. Since 1990s, however, mECT remains the most effective treatment for treatment-resistant depression.

As with other clinical practices, ECT did not include IC in its routine practice prior to the 1950’s when, according to the literature, patients’ eyes were covered to prevent them from seeing what the doctor would do. Some hospitals would have other patients observe the invoked seizure to as a means of controlling behavior. ECT was also occasionally performed on hypnotized patients who neither received proper information nor gave prior consent for the treatment.

In 1991, the UN adopted the Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care, a resolution that was to have subtle effects on clinical psychiatry in Japan. In a 1993 survey, about half of Japan’s hospitals said that they would explain ECT at least to the patient’s family. In 1997, all hospitals sought IC from the patient’s family while 41% went directly to the patient for IC.

However, IC for ECT still poses a challenge for clinicians. Patients with severe depression may be delusional, severely retarded or overcome with thoughts of suicide and therefore are often unable to understand treatment options sufficiently to give consent. Hence, clinicians are faced with a dilemma, ‘Should we side-step patient volition in order to save a life?’ The United Kingdom has established a legal system that can force some patients to receive ECT when such treatment is indicated, but no such law exists in Japan.

The case below illustrates some of the issues surrounding the use of informed consent with ECT.

*Case:* A 35 years old female was hospitalized with catatonia, a form of schizophrenia characterized by mutism, rigid posture and bizarre behaviour. She was resistant to all pharmacological treatments. ECT is recommended for catatonia. Attending physician tried to explain to her about the ECT procedure. Although mute throughout her hospitalization, she spoke immediately following this explanation. She said, ‘NO!’, and her family obeyed her wishes. Her catatonic state lasted 4 months with no improvement until the attending physician asked an elderly female patient, a nurse, who successfully received ECT for depression. Following the woman’s explanation, the
patient consented to ECT. She recovered from catatonia within a couple of weeks.

**Informed consent in clinical research**

The speaker’s work in genetic and neuroimaging research requires a number of bureaucratic procedures, including consent forms from subjects. Explanation forms and consent forms must be submitted with the research plan to the ethics committee to be examined. Among similar research projects on the molecular genetics of mental disorders, in 1994, a single informed consent form had 409 Japanese characters, whereas in 2005, a 18,049 character research plan devoted 7408 characters to the informed consent form. (Note: One Japanese character corresponds to 2-3 western typed characters.)

Accompanying this content increase in consent forms is the concern that subjects may not really appreciate the research content or the conditions of research participation.

In current practice, the written information in the IC form is supplemented with oral explanation in the ‘patient’s own language’.

**Current problems and future directions**

IC was introduced to preserve the rights of subjects participating in clinical research as well as those of patients receiving care, but who actually benefits from IC is uncertain. In litigious countries such as the United States, IC is used primarily to protect clinicians and researchers from lawsuits and a significant amount of time is spent getting IC in daily clinical practice. The medical costs in Japan, however, are three times lower than in the US, and Japanese physicians spend less time seeking IC. Japanese physicians do get formal and full IC for invasive treatments like surgery, but no formal IC for daily pharmacotherapy. Written materials that the patient receives from the pharmacist and accompanying oral explanations are insufficient but do provide some compensation for the lack of IC used with drug administration.

IC does benefit participants/patients, but it also distributes the associated risks evenly between the patient, clinicians and researchers. *Jiko-Sekinin* was last year’s buzzword in Japan. It translates into self-responsibility and originated in the context of volunteers who continued to work in Iraq despite warnings issued by the Japanese Government. This term also reflects another meaning behind informed consent: take responsibility.
Summary

In summary, Japan’s acceptance of informed consent happened far later than Western countries, most likely because of cultural differences in medical practice and social structure. Difficulties in getting informed consent also exist in various areas of medicine including psychiatry, and the more extensive application of informed consent in Japan is starting to bring several practical issues to light.
SESSION IV

“SOCIAL RESPONSIBILITY: PUBLIC HEALTH AND HEALTH CARE”

- Mr (Prof.) Adolfo Martinez-Palomo (Mexico)
- Mr (Prof.) Hans Galjaard (The Netherlands)
- Mr (Prof.) Yasuhiko Morioka (Japan)
Global health conditions at the beginning of the new century are marked by growing inequities related mostly to poverty and lack of access to health care services. Health policy has been considered recently to be more than the provision and funding of medical care, by taking into consideration that for the health of the population as a whole the social and economic conditions that make people ill and in need of medical care are clearly of utmost importance. These include, among others, the lifelong importance of health determinants in early childhood, and the effects of position in the social ladder, poverty, drugs, working conditions, unemployment, social support, adequate food and transport policy. In contrast, the influence of biological and physical factors on health has been estimated as less than 15% and 10%, respectively.

It is an accepted fact that more than one billion people – one sixth of the total population of the world – live in extreme poverty, lacking the safe water, proper nutrition, basic health care and social services needed to survive. Poverty is reflected in various aspects of the life of individuals and populations living under deprived conditions in developing countries, but also in some regions of industrialized countries. There is poverty in food, which is scarce in quantity and deficient in quality; there is poverty in housing, which nearly always is inadequate, and there is poverty in knowledge, education and culture. Finally, there is poverty, which approaches real misery that involves the hygiene of persons, houses and the community.

Global health conditions at present have been summarized by the World Health Organization (WHO):

**Social Responsibility:**

**Public Health and Health Research**

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In this first decade of the 21st century, immense advances in human well-being coexist with extreme deprivation. In global health we are witnessing the benefits of new medicines and technologies. But there are unprecedented reversals. Life expectancies have collapsed in some of the poorest countries to half the level of the richest – attributable to the ravages of HIV/AIDS in parts of sub-Saharan Africa and to more than a dozen ‘failed states’. These setbacks have been accompanied by growing fears, in rich and poor countries alike, of new infectious threats such as SARS and avian influenza and ‘hidden’ behavioral conditions such as mental disorders and domestic violence. The world community has sufficient financial resources and technologies to tackle most of these health challenges; yet today many national health systems are weak, unresponsive, inequitable – even unsafe. What is needed now is political will to implement national plans, together with international cooperation to align resources, harness knowledge and build robust health systems for treating and preventing disease and promoting population health.

In addition, recent analyses indicate that the disease burden imposed by neglected tropical diseases has been underestimated. They not only cause approximately 530,000 deaths annually, but also produce much more long-term disability, disfigurement and suffering, resulting in a loss of up to 57 million disability-adjusted life years annually.

The guiding principles of most governments have been those of equality of access to health care and solidarity in sharing the financial burden proportionate to income. However, pressures on health-care systems are already imposed by the impact of financial and demographic determinants. These factors were recognized almost 30 years ago in the development of international strategies for health promotion, such as the WHO commitment to a global strategy for Health for All and the principles of primary health care through the 1978 Declaration of Alma Ata. Today, after not being able to reach health for all in the year 200, health promotion is still a crucial topic of debate.

Subsequent international health policy guidelines have promoted health as a basic human right, essential for social an economic development. It has been considered that health promotion, through investment and action, has a marked impact on the determinants of health so as to create the greatest health gain for people, to contribute significantly to the reduction of inequities in health, to further human rights, and to build social capital. The ultimate goal is to increase health expectancy and to narrow the gap in health expectancy between countries and groups.

Social responsibilities for health are a fundamental concern for the ethics of professional public health practices. Central concerns are account-
ability and commitment and the reliable performance of professional tasks in the pursuit of social goods.

The promotion of social responsibility for health was first established as a priority at the WHO Fourth International Conference on Health Promotion: New Players for a New Era – Leading Health Promotion into the 21st Century, held in Jakarta in 1997. The conference recommended that decision makers must be firmly committed to social responsibility and both public and private sectors should promote health by pursuing policies and practices that:

- avoid harming the health of individuals,
- protect the environment and ensure sustainable use of resources,
- restrict production of, and trade in, inherently harmful goods and substances such as tobacco and armaments, as well as discourage unhealthy marketing prices,
- safeguard both the citizen in the marketplace and the individual in the workplace,
- include equity-focused health impact assessments as an integral part of policy development.

The topic of social responsibility for health was further discussed at the WHO Fifth Global Conference on Health Promotion: Bridging the Equity Gap, held in Mexico City in 2000. Five broad themes emerged from the discussions among conference participants:

- what constitutes social responsibility for health,
- how do you measure it,
- issues of equity and gender,
- case studies and what they reflect in terms of the prerequisites of success,
- cultural diversity.

It was clear from the participants’ discussion that social responsibility, like health, means different things to different people. Defining it becomes particularly important when identifying who is responsible for what. In working together, people need to be clear about rights and responsibilities and need to go through a process of defining social responsibility for health in their own terms, so that there is collective ownership. Some participants felt that governments too often sign up to human rights but fail to follow through and support them at the local levels. However, if social responsibility is devolved, governments too often give up their own responsibilities. A key challenge is to link the different levels of society and develop a dialogue to overcome the inherent tensions. Some participants pointed out that both
workplaces and trade unions have a role to play. Trade unions in particular were considered under-utilized allies.

More recently, the WHO Sixth Conference on Global Health Promotion held in Thailand in August 2005, identified in the Bangkok Charter actions, commitments and pledges required to address the determinants of health in a globalized world through health promotion. Among the key commitments to make the promotion of health a core responsibility for all of government was identified. Thus, it was recommended that governments at all levels must tackle poor health and inequalities as a matter of urgency because health is a major determinant of socioeconomic and political development. Local, regional and national governments must give priority to investments in health, within and outside the health sector, and provide sustainable financing for health promotion. To ensure this, all levels of government should make the health consequences of policies and legislation explicit, using tools such as equity-focused health impact assessment.

In October 2005, the UNESCO General Conference adopted by acclamation the Universal Declaration on Bioethics and Human Rights, which includes the principle of social responsibility and health, stating that:

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

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

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

Further international efforts to meet the needs of the poorest, including better health, have been included in the eight UN Millennium Development Goals (MDGs). These range from halving extreme poverty to halting the spread of HIV/AIDS and providing universal primary education. The UN concrete action plan to reverse poverty, hunger and disease affecting billions of people was presented in 2005. It was considered that the consequences of poverty reach far beyond the afflicted countries. Poverty,
inequality and disease are chief causes of violent conflict, civil war and state failures. Therefore, a world with extreme poverty is a world of insecurity. The Millennium project takes into consideration that the world already has the technology and know-how to solve most of the problems faced in the poor countries. The goal is to achieve the following eight goals by the year 2015:

- eradicate extreme poverty and hunger,
- achieve universal primary education,
- promote gender equality and empower women,
- reduce child mortality,
- improve maternal health,
- combat HIV/AIDS, malaria and other diseases,
- ensure environmental sustainability,
- develop a global partnership for development.

The United Nations accepts that there is barely time to achieve the goals, because the window of opportunity is closing. A major global policy break-through is needed to get the poorest countries on track to meeting the goals. Although critics have claimed that poverty reduction strategies are in essence a collection of development policies that have been tried and failed in the past, the answer has been that the project is based on addressing simultaneously many needs with a large number of proven, highly effective, low cost interventions. However, according to many assessments, the world will fail to achieve the Goals by 2015 and, in particular, many countries and regions will fall substantially short of health targets.

At recent parallel meetings of the Forum 8 organized by the Global Forum for Health Research and the Ministerial Summit on Health Research, held in Mexico City in November, 2004, over 1,400 policy makers, health ministers, researchers and representatives of governments, development agencies and research institutions examined the issue on how research could improve strategies and help to attain the MDGs. One of the conclusions of both the Forum and the Summit was that achieving the Goals will require addressing health and its determinants in a comprehensive way and will necessitate further health research, of high quality, focused on the needs of developing countries and vulnerable populations. It must give systematic attention to cross-cutting issues of poverty and equity, taking account of inequities based on gender, ability, ethnicity, and social class, among others; the needs of both the aged and the largest generation ever of young people 0-19 years, and the needs of other specifically disadvantaged groups such as migrants, refugees and those exposed to violent conflict. It was concluded that all the participants must commit themselves to the
shared responsibility of advancing the volume and pace of health research that is focused on improving the lifespan and health of people everywhere. Special consideration was given to increase funding for health research in systems research, as it is this activity of research the one that may have the largest contribution to deliver the already known interventions to improve health.

A specific recommendation on research funding was made at the end of Forum 8, stating:

To provide the resources necessary for essential research within developing countries, we urge governments of those countries to spend at least 2% of their national health budgets on health research, as recommended by the 1990 Commission on Health Research for Development. These funds should be used locally for health research and research capacity strengthening. Also in line with the Commission recommendation, donors are urged to allocate 5% of their funding for the health sector to health research and research capacity strengthening in developing countries. Monitoring the use of funds for capacity development is a vital complementary activity.

The point here is how governments perceive research. If they see research as an expenditure and not as an investment, the amount of funds will be scarce, mainly when the funds in poor countries have to be distributed among greater needs, relegating health research as an expenditure and one activity that is not a priority, falling with this into a vicious cycle that will not make it possible to improve social determinants of health. But also, we come to a basic question: is there a greater need than health, as a key determinant to development?

Development agencies have challenged the pharmaceutical industry to improve its efforts to tackle the health crisis affecting developing countries. They consider that a socially responsible company should have policies on access to treatment for developing countries which include the five priorities of pricing, patent, joint public private initiatives, research and development and the appropriate use of drugs. They comment, in addition, that the industry currently defines its policy on access largely in terms of philanthropic ventures and that critical challenges remain, particularly the issue of pricing.

Pharmaceutical companies are commercial enterprises, almost exclusively focused on generating maximal returns for their shareholders. Recently, however, new projects have a distinctly charitable aspect and will not generate profits. Examples include the new Institute for Tropical Diseases in Singapore for the discovery of drugs for tuberculosis and dengue and a considerable number of projects aimed at new treatments for
malaria, elephantiasis, river blindness, HIV/AIDS, leprosy, dengue and sleeping sickness.

A number of alliances with public, private, nongovernmental and international organizations and civil society have been organized with the aim to address the determinants of health in a globalized world through health promotion. Two recent ones are describes below.

The Grand Challenges in Global Health initiative is a partnership dedicated to supporting scientific and technical research to solve critical health problems in the developing world. The initiative’s partners are the Bill & Melinda Gates Foundation, the Canadian Institutes of Health Research, the Foundation for the National Institutes of Health and the Wellcome Trust. A grand challenge is meant to direct investigators to a specific scientific or technical breakthrough that would be expected to overcome one or more bottlenecks in an imagined path towards a solution to one or preferably several significant health problems. Therefore a grand challenge is envisioned as distinct from a simple statement of one of the major problems in global health, such as malnutrition or the lack of access to medical care. The initiative has identified and supported seven long-term goals to improve health in the developing world:

- to improve childhood vaccines,
- to create new vaccines,
- to control insects that transmit agents of disease,
- to improve nutrition to promote health,
- to improve drug treatment of infectious diseases,
- to cure latent and chronic infection,
- to measure health status accurately and economically.

The Reaching the Poor Program (RPP) is an effort to begin finding better ways of ensuring that the benefits of health, nutrition and population (HNP) programs flow to disadvantaged population groups. It has been undertaken by the World Bank, in cooperation with the Gates Foundation and the Dutch and Swedish Governments. In order to help improve how well HNP programs reach poor people, the RPP seeks to:

- Determine which HNP programs do and do not reach disadvantaged groups effectively. The resulting information, produced through application of recently-developed quantitative techniques for assessing programs’ distributional performance, is intended to provide guidance to policy makers about which approaches to adopt and to avoid in developing pro-poor initiatives.

- Encourage others to undertake similar determinations of HNP program effectiveness in reaching the poor. More widespread application
of the recently-techniques just mentioned, derived from the ‘benefit incidence’ approach used to determine who benefits most from government expenditures, would allow policy makers to assess and then improve their performance in reaching the poor on an ongoing basis.

The programme considers that health policies do not have to be inequitable: ‘While most health, nutrition, and population services exacerbate poor-rich inequalities by achieving much lower coverage among disadvantaged than among the better-off, many significant and instructive exceptions exist. These demonstrate the feasibility of reaching the poor much more effectively than at present, and point to promising strategies for doing so.’

In conclusion, the widening gaps in health conditions described above are best explained in terms of social, economic and cultural differences and the value that individuals and societies attribute to the idea of a healthy society. Therefore, individual responsibility and social responsibility are usually inextricably intertwined and are related to moral judgments and political strategies that may or may not seek equity as a goal.

Health is everyone’s responsibility: the public and private sectors, governments of developed and developing countries, NGOs, multilateral agencies and civil societies, and obviously, individuals.

References

During the past decade the International Bioethics Committee of UNESCO (IBC) has mainly focused on ethical aspects associated with new technologies in assisted reproduction and the application of new genetic methods. In the debates different views mainly concerned the definition of the beginning of life and the related issues of respect for the inherent dignity of a human being.

Though important as an ethical problem research and diagnostic analysis of early stages of human embryonic and fetal development are quantitatively negligible compared to the vast number of terminations of pregnancies associated with cultural and socioeconomic factors and the inaccessibility of legal abortion.

In this context it is of great importance that the most recent UNESCO Universal Declaration on Bioethics and Human Rights contains Article 13 on social responsibility.

Here, poverty, illiteracy, lack of access to basic needs including quality health care is considered as an important ethical issue. This is also in agreement with emerging trends in ethics as recently described by Knoppers and Chadwick (2005). These authors state that ‘ethics does not consist of a static set of theories or principles that can unproblematically be applied to new situations’ and then continue by extending existing norms with those of reciprocity, mutuality, citizenry and universality.

It is indeed impressive to read the UN report on differences in the world. Prof. Martinez already mentioned the lack of basic needs illustrated by more than a billion people who have no access to clean drinking water, sanitation and adequate nutrition. Around 800 million people are undernourished, have no access to proper health care and/or are illiterate (two-thirds of whom are women).

To change this situation it is essential to improve the status of women. In the IBC Drafting Group preparing the declaration on universal norms on bioethics it was proposed to include in the article on social responsibility ‘the right of reproductive choice for women’.

The IBC later preferred the term ‘access to reproductive health’ but the governmental experts in their June meeting (2005) in Paris decided to omit referral to reproduction altogether and replace it by the general expression ‘health of women and children’. This is especially regrettable since three months later in New York the world’s Heads of State formulated ‘needs of universal access to reproductive health’ both in article 57 on HIV/AIDS and in article 58 on gender equality.

I am afraid that the choice by UNESCO’s governmental experts of a more conservative position than their Heads of State will put our Organization at the background of the important process of women’s emancipation.

This process is not only important for women themselves but also for future generations of children. Whereas in wealthy countries couples who give birth to a child have a > 99% chance to see their child growing up to adulthood, in the developing countries each year 14 million children have no chances at all because they die; this seems to me indeed an ethical issue of great priority.

According to the 2005 UNFPA report, the highest life expectancy is in Japan and Norway (M/F 78.7/85.8 years) and the lowest in Swaziland (31.6/31.3 years). One third of the mortality in low-income countries is poverty related and 42% can be prevented compared to 6% in wealthy countries. In the latter high priority is given by citizens, governments and companies to health research and development and globally about $73 billion is spent. Unfortunately only 10% of this effort is spent on 90% of the world’s disease burden and 90% of the budget is dedicated to the 10% of disease that are of importance mainly in high-income countries.

The burden of disease, defined as loss of quality adjusted life years, is different between high and low-income countries although among the main 10 diseases there are also similarities like cardiovascular and mental diseases\(^4\).

In the wealthy countries nearly every year new diagnostic methods become available and to a lesser extent new therapies. Most of the latter are costly which is partly done to the extremely high costs of development of a successful drug (between $500 -1000 million).

During the period 1975-1997 more than 1200 new drugs reached the global market but only 13 (1\%) were directed against tropical disease. Only a small minority of HIV carriers in developing countries have access to medicines that change AIDS from a fatal disease to a chronic handicap.

Some large developing countries like Brazil, India and China have started their own pharmaceutical companies, sometimes neglecting existing patents. In some instances this has led to the availability of cheaper medicines. In other situations the WTO has forced developing countries to obey patent legislation, thereby blocking export of cheap medicines from countries like India to Africa.

Are there expectations for improvement? Not under present circumstances. Nearly all basic research in biomedicine is carried out in wealthy countries with a major role of the United States of America and Europe.

As can be deduced from the Nobel Prizes during the past decades most of the innovative research concerned the translation of genetic information to protein structure and in some instances the development of new diagnostic methods with great impact (like nuclear magnetic resonance, helicobacter as a course of gastric ulcer).

Because of the increasing costs of health care in the wealthy countries (varying from 8-15\% of GNP) there is increasing pressure to direct research in biomedicine towards early diagnosis, therapy and prevention of diseases that cause mortality and chronic handicaps. There are no signs of major changes in research direction towards important health problems in developing countries.

At a recent conference in Cambridge (United Kingdom) organized by the Wellcome Trust and the European Community\(^5\) it was striking to see

\(^5\) From biobanks to biomarkers; Translating the potential of human population genetic research improve the quality of health of the EU citizens. Wellcome Trust Conference Center. Huxton, UK, 20/21 September 2005.
how many research groups in at least 10 European countries were conducting or planning large scale population studies where individual health data are being linked to specific DNA sequences and in some instances to environmental factors. New technologies enable the analysis of tens of thousands of gene sequences, gene expressions or proteins and new ways of bioinformatics will handle the enormous amounts of information. In the United Kingdom no less than 500,000 people aged between 40-69 years will be involved in such a study.

It is likely that human population genomics will yield new information about linkage between genetic factors and disease and also about the genetic basis of variability in response to therapy. However, such linkages will have to be translated into molecular pathogenetic mechanisms and this requires ‘classic’ laboratory approaches. Even when a new cellular mechanism or clinical/biological substance is discovered and patented it takes an average of 10-12 years before a new medicine is in the market.

In the mean time it is an unresolved problem how new findings of for instance an increased disease risk at the population level should be translated to an individual patient. Within IBC the concern has already been expressed about the tension between the interest of the individual and that of society. Although UNESCO has issued an International Declaration on Human Genetic Data (2003) new and large scale developments in the area of population genomics will require re-consideration of the issues. How will population data be translated to the individual (at risk?). Can people cope with (negative) information about their future health and how do experts deal with the diversity among people also in their reaction towards such information. Will relationships be influenced both with partners and families and sometimes within specific communities. In which way will third parties use information about people’s individual or group risks. And of course the complex issue of sharing benefit will arise again and at a larger scale when hundreds of thousands people will be involved in population genomics-studies. Finally we have to prepare ourselves in time for a possible shift from knowledge about disease mechanisms to that about the biological background of normal physical and behavioral characteristics. No doubt that the ethical aspects of all these issues require thorough attention.

My main concern is that scientists, health professionals and public/private organizations in the wealthy countries will become more and more occupied with these large scale population studies and their consequences and that no change of direction towards the problems of the developing world will occur.
The only solution I see is that researchers, health professionals and organizations of developing countries will become involved in some of the new projects mentioned. Such representatives may accomplish that also their part of the global burden of disease will be incorporated in some of these modern studies. People from wealthy countries should not under-estimate the knowledge and motivation of their counterparts in developing countries and also be aware of ‘the value’ of citizens of specific ethnic groups in terms of research and with the positive goal of elucidating health problems important for these groups.

One major advantage of our present world is the rapid development of new and easy communication methods and hence of information exchange. Put more emphasis on the design of multinational projects including developing countries, establish a reasonable division of labor including authorities and experts from developing countries, create the necessary budget and be honest in the sharing of benefit, varying from joint publications to the availability of new methods of early diagnosis, treatment and prevention. That would be an example of social responsibility.
SOCIAL RESPONSIBILITY: PUBLIC HEALTH AND HEALTH CARE

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Today’s theme has been drawn from Articles 14 to 17 of the Universal Declaration on Bioethics and Human Rights, a theme which, I think, clearly reflects the meaning of these articles. As a surgeon, I began thinking about ethical issues in medical practice when I was nearing retirement from Tokyo University. Today, I would like to comment mainly from the standpoint of a clinician, citing particularly current cases in Japan.

When we think about social responsibility in public health and in health care, we have to take into consideration certain facts: the fact that the world is still witness to war and terrorism; the fact that some countries are in possession of deadly armaments including weapons of mass destruction such as atomic bombs; and the fact that a great number of people still suffer from poverty and hunger. These things constitute a direct threat to people’s lives and are linked to many factors such as conflict between races and religions and to population problems. The root of all this may be people’s egoism. Even though these problems seem extremely difficult to resolve, I hope the United Nations and UNESCO will continue to tackle them.

In this climate, nations and societies also face, and need to resolve, a lot of difficult problems on a daily basis.

Public health primarily aims to ensure the health of people as a group. Needless to say, the human rights of each individual should be a mandatory consideration. However, in many cases, the well being of a society or a group takes priority over the individual. In this respect, the responsibilities of societies or nations are becoming increasingly important, responsibilities including the need to develop measures for environmental problems such as pollution and global warming and also for viral infectious diseases such as
AIDS and bird flu. These problems require a global perspective rather than one which focuses on a particular country. It is especially important for countries to cooperate on a global basis and exchange and share information on public health as well as to suggest measures for the general improvement of the environment in each country. I believe that organizations such as the World Health Organization (WHO) are nowadays making significant contributions in this respect. In addition, there are other critical issues societies need to tackle such as the control of lifestyle-related diseases.

In health care, there are questions such as health promotion, the prevention and treatment of diseases and nursing care. These days, it is widely accepted that the government has a responsibility to secure healthy and culturally fulfilling lives for all its citizens. To meet these obligations, countries are working on issues including improving medical and nursing-care facilities, training health care, nursing and other care professionals, and ensuring the public has equal access to facilities and services. However, these challenges require significant financial resources which, even in developed countries, are limited. In reality, it is difficult to meet all the needs of all the people in each nation of the world.

When looking at current health-care policies around the world, we can see two types: One type of policy aims to provide individuals with the greatest range of health-care choices and results in a certain degree of inequality which is tolerated - the United States is a prime example of this type. Nations adhering to the other type of health-care policy try to provide an equal level of health care to all its citizens through public health insurance - this is the case with many European countries and also Japan. Many countries endeavour to manage health-care services by coordinating public funds and individual contributions according to the financial basis of each country.

Japan introduced a universal health insurance system in 1961. This gave all citizens access to medical institutions anywhere in the country at a lower cost compared to other countries.

The ratio of national health expenditures to GDP is often used as an indicator to compare the health costs between countries. The ratio for the United States of America is extremely high, while Japan’s is much lower than all European developed countries except the United Kingdom.

And yet, according to a WHO report, Japan is ranked top in terms of healthy life expectancy and is given a high evaluation for health care in terms of effectiveness, equality and access. Of course, there are various domestic issues such as complaints from patients or conflicts between the government and the Japan Medical Association over medical fees. However,
in general, all Japanese citizens have access to medical institutions for a relatively low cost. This is only possible due to the dedicated efforts of physicians and other health professionals in Japan, and is one aspect of the Japanese health-care system of which we are very proud.

However, the increasing elderly population in Japan is inflating health costs significantly; a problem exacerbated by the rapid transition to an aging society with a decreasing birth rate and economic stagnation. In addition, there are many elderly people who require long-term, or in-house nursing care. The combination of these factors has led to mounting concern that the financial burden on the government and on the insurers is coming close to its limit and that the resulting containment of health expenditure and political measures to shift more of the costs onto patients will limit access to health care and increase inequality in health care provision. To cope with this situation, efforts have been made to establish nursing-care facilities for these people and a Long-term Care Insurance System was created in 2000. However, this insurance system is now facing the same sorts of problems as the universal health insurance. In the five years since the start of the system, public finances for health insurance have worsened, leading to the decision to increase the co-payment of those who are receiving care in this insurance system. Everyone seeks the best health care and services. However, financial resources are limited which makes it a difficult situation to resolve. It is the responsibility of the government to decide how much should be allocated to which areas of the society.

The issue of medical ethics is now becoming particularly important for physicians and other health professionals.

1) Ideas such as respect for patients’ autonomy and informed consent in medical practice are intended to protect the human rights of patients. For the last 20 years or so these fundamental concepts have also been adopted in Japan and it is currently legally recommended that physicians seek patients’ informed consent.

2) Issues related to emotions such as compassion for patients and the spirit in which services are provided are also regarded as a valuable aspect of health-care provision in Japan.

3) Physicians are expected to provide equal treatment, without discrimination.

4) Physicians are expected to consider social issues from many perspectives during their daily practice.

It is particularly important to be aware of the wider social background in health fields such as health economics, terminal care and reproductive medicine. A wide scope of ethical issues is now assigned to physicians.
Ethics is basically a personal issue. However, in practice, it is necessary to set rules that are acceptable to people and to ensure that they are adhered to. To do so, it is important that physicians’ professional organizations, such as medical associations and specialist societies, set their own ethical rules and comply with them. Very fundamental ethical issues should be regulated by the government through legislation; however, governmental organizations can also issue administrative guidance in place of legislation such as through government regulations and guidelines. In countries with high litigation, court precedents, rather than laws serve as ethical regulation. Thus there are many ways for ethical regulation to be established depending on the country. In the United States of America, for instance, there are only very limited legal regulations in the field of bioethics, while European countries appear to have stronger regulations. Japan falls between these two with a small number of laws related to bioethics because administrative guidance from the government and self-regulation by medical associations or specialist societies are common.

In the area of public health and health care, there is a distinction between the responsibility of individuals, organizations and the government. The relationship between them varies from country to country. However, the government should take a leadership role in this respect.

I would now like to explain the Japanese approach to public health, health care and human rights issues related to these fields.

First of all, let me clarify the way in which the concept of informed consent has been integrated into Japanese medical practice. As you know, this concept was developed in the United States and Europe in the late 20th century to protect the human rights of patients and to respect his/her principle of self-determination. This concept has been regarded as important in Japan for the last 20 years or so. Many Japanese accept this concept as an important medical principle that helps build trust or good human relationship between patients and physicians rather than one that protects human rights. Japanese especially value doctors’ love and compassion for their patients in the patient-physician relationship. In this respect, there seem to be some differences between Japanese and Europeans in that Japanese are uncomfortable with the concepts of ‘human rights’ or ‘rights’ more generally.

Ms Ayako Sono, a popular Japanese intellectual, a Christian, and a novelist, is often noted for saying: ‘I dislike people who claim human rights. What we need is love’. It can also be said that many Japanese think that: it is better not to make a scene by claiming an infringement of human rights or rights and it is more humane to endure minor discomfort and lead a happy life helping each other.
About 140 years ago, Japan abandoned its isolationist policy and accepted western civilization and culture. Japanese people then came in touch with western ideas of rights, droits, and human rights, which had never existed in their culture before. Various translations for these ideas were coined and finally kenri (rights) and jinken (human rights) in Chinese character were accepted. These words later crossed the sea and have since been used in China also. It is interesting to note that the ken of kenri means ‘power’ and the ri means ‘Interest’, meaning to protect one’s interest with power. There is a sense of egoism in the meaning of this word. One could argue that it is a bad translation, but there is no other suitable Japanese word to explain its meaning. Despite the bad translation, most Japanese seem to understand discussion of ‘rights’ and ‘human rights’ in the western sense. However, insisting on one’s own rights can conflict with other people’s rights. Japanese have a strong tendency to dislike this kind of conflict and many have a feeling of dislike for those who provoke it.

This tendency originates in the social and cultural characteristics of the Japanese. Unlike many western countries, this country consists largely of a single race, and has therefore a familistic background. Of course, these days, Japan is becoming increasingly westernised and the values and mentality are changing, especially among younger people. However, I think we can still say that in some fundamental respects present-day Japan remains unchanged.

After the French Revolution at the end of the 18th Century, the French were claiming ‘freedom’, ‘equality’ and ‘fraternity’ as their slogans. By contrast, in recent years, in the field of medical ethics I see mention of freedom, autonomy and equality, but less of ‘fraternity’ or ‘humanity’ which originally comes from a ‘respect for human dignity’. We all, including those of us in the field of health care, need to go beyond egoism and feel fraternity, love or compassion for others. The provision of more appropriate health-care training and the cultivation of human resources is a most important part of the responsibilities of our society.
SÉANCE V
« LES QUESTIONS D’ACTUALITÉ DE LA BIOÉTHIQUE — LES PERSPECTIVES ASIATIQUES »

PARTIE I : QUESTIONS SENSIBLES DE LA BIOÉTHIQUE ASIATIQUE

- M. (Prof.) Renzong Qiu (Chine)
- M. (Prof.) Chog-Lek Koh (Singapour)
- Mme (Prof.) Satoko Tatsui (Japon)

PARTIE II : LES DIFFÉRENTES PERSPECTIVES ASIATIQUES DE LA BIOÉTHIQUE

- M. (Prof.) Leonardo De Castro (Philippines)
- M. (Prof.) Luong Le Dinh (Viet Nam)
- M. (Prof.) S. Qasim Mehdi (Pakistan)
- M. (Prof.) Prakash Narain Tandon (Inde)
CULTURAL DIVERSITY IN BIOETHICS

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Abstract

This paper first will argue against both ethical universalism and ethical relativism. Neither universal ethics nor ‘global bioethics’ is valid if they mean an overarching ethical theory with full content. The fact that bioethics is now become more and more global does not mean that bioethics in different cultures will converge into one united bioethics. Even within one culture bioethics has different approaches and from them different paradigms of bioethics may be developed, let alone bioethics in different cultures. There are some fundamental values which are shared by different cultures, such as respect for person, non-maleficence, beneficence, justice and solidarity. However, these values are rooted in different theoretical frameworks which in turn are entrenched in different cultures. For example, all these fundamental values in Confucianism are elements of the art of ren (humanness or humaneness), so the priority and focus would be different from other cultures. One is the different value put on family in Chinese culture in contrast with its western counterpart, and the other is more emphasizing of duties or responsibilities than rights. After assimilating valuable elements from western culture the attempt has been made to develop approaches in which there would be more balance between individuals and family, and between duties and rights.
DEMYSTIFYING THE HUMAN GENOME,
BIOETHICS AND HUMAN RIGHTS

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Abstract

The Universal Declaration on the Human Genome and Human Rights, the International Declaration on Human Genetic Data and the Universal Declaration on Bioethics and Human Rights were adopted by the General Conference of UNESCO on 11 November 1997, 16 October 2003 and 19 October 2005, respectively, and Member States have been encouraged to implement them. However, the task of implementing these Declarations in many Member States will not be easy because a large proportion of the people of these Member States are not familiar with or do not understand the concepts of the science and scientific information involved, respect for privacy, confidentiality, non-discrimination, informed consent, bioethics, human dignity and human rights. Hence, there is an urgent need for many Member States to actively promote education, awareness-raising, consultation and public debate so that their citizens are familiar with the principles and issues of bioethics and then able to participate in the implementation of these Declarations.
1. Introduction

If bioethics has reverence for the existence and life of human beings at the root, I can say bioethics or at least similar thing has been existent in Japan. Therefore the attempt to establish universal principles of bioethics will be favourably received in the abstract by Japanese or other Asian people. Bioethics from the Western world had already a great influence upon us, before we could discuss 'our own bioethics' thoroughly enough. Through learning from the Western world, we have made a progress. At the same time, however, because of lack of discussion, we have some difficulties in policy making. If we swallow the proposal by Western-origin bioethics without digestion, we will surely make a mistake. Conflicts on the surface between our bioethics and theirs can be an obstacle to our decision making. I would like to talk about two topics, which are of special meaning to our bioethics : abortion and organ transplantation.

2. Abortion

Abortion done during twenty-two weeks of gestation is de facto decriminalized in Japan. However, this is not the result of a positive policy making.

Traditionally, we did not have such a strict legal ban on abortion that we accepted from Europe together with the modern criminal law. A strict ban on abortion was a suitable way to enhance the wealth and military strength of the country and the corresponding provision was utilized to a greater extent
than expected. The ban was not absolute and subsequently conditions were arranged from an eugenic point of view.

After the World War II, the poverty-stricken country was unable to endure a further population increase. As a result of extended interpretation of the scope of the provision, de facto decriminalization has come. Now, no one is accused of abortion done during twenty-two weeks of gestation. But the counterfactual law situation has been retained. We have done nothing except deleting the notably eugenic part from the law. Literally, abortion is a crime regardless of gestational age, which is also an official (governmental) interpretation. How should we cope with this situation?

Should our law and official view be valued for its pro-life tendency? Or should we make a new practical law to protect the foetus and punish abortion? The word ‘respect for life’ seems beautiful enough to hide our problem. Knowing that our country has never shown serious concern for either the foetus’ life itself or the fundamental reproductive right, accepting ‘respect for life’ policy is too simple.

We are facing a lot of issues concerning an unborn child and its life; antenatal diagnosis, selective abortion, scientific research using embryos and so on. We also use ‘human dignity’ or ‘respect for life’ often as key words to solve problems. But this kind of discussion is substantially empty, the central problem of ‘human dignity’ and ‘respect for life’ being left in the air. Needless to say, applying the bioethics from the Western world would not bring us the right answer.

3. **Organ transplantation**

We established the Organ Transplantation Law in 1997, which provided the conditions of organ transplantation from dead donors including brain-dead donors. In spite of long and intensive discussions, our law does not work very well. Only 40 organ transplants from brain-dead donors have been executed under this law (the number of donors). Since the law requires a written living will of a donor, children having not enough mental capacity cannot become a donor. The advocates of organ transplantation are suggesting a modification of the law, and the opponents are demanding for abolition of the law. Only people who do not want to make things clear are satisfied.

The definition of death is the most basic problem to solve, but it is still a controversial issue in Japan. Carefully choosing words, our law avoids answering the question. Furthermore, the law requires a written living will of a donor for doctors to diagnose the donor’s brain death legally and to remove
organs from the donor. It seems as if the law provided a donor with the right to determine when s/he is dead.

The Organ Transplantation Law is supported not only by people who do not want to decide but also people who do not accept brain death as death. But many of them are not against organ transplantation from brain-dead donors as such. Most of the lawyers and people who actively support organ transplantation criticize their way of thinking behind it. They argue, 'it is not allowed to remove hearts from living donors, it is not allowed either to accept the right to determine the death'. This is sound. Not to decide is not a virtue, and the 'Japanese way of thinking' and 'Japanese tradition' is not an all-around argument.

On the other hand, this sound argument sometimes goes too far. Some say 'we should admit rationally that brain death is death and adopt the western way. Transplantation is 'a gift of life,' we should adopt the opt-out system of donation decision'.

If we support organ transplantation from brain-dead donors, we should admit that brain death is death. This is sound. But we need to understand how the majority of people see it. Most people who do not necessarily accept brain death as death are not insisting on the fundamental human rights of brain-dead donors, nor sufficient medical treatment for brain-dead donors. They simply think that they cannot regard brain-dead people as dead bodies, that they do not want to bury them as dead bodies, or that they themselves do not want to die deaths in which doctors hurry to them and take them away from their family. Is that way of thinking uniquely Japanese? Probably not.

Understanding that our Organ Transplantation Law, which requires a donor’s written living will to legal brain-death diagnoses and organ removal, provides the right to choose how to say good-bye to the world, we do not find any inconsistency and unfairness there. And I suppose this is reasonable enough to be understood by people from other cultures.

Japanese people, when they feel out of place in the Western world, sometimes get off with the word ‘Japanese tradition.’ But using the words ‘Asian’, ‘Japanese’ as key words lead to abandonment of justification and refusal to be understood by the world community. On the other hand, it is not beneficial to suppress opposition to the Western-coloured universalism. We have to express ‘our bioethics’ in universal language, and ‘Asian perspectives’ will contribute to building up the universal principles of bioethics then.
Providing an Asian Character to the Globalization of Bioethics

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Abstract

Globalization in various areas that relate to bioethics is taking place at a pace that is too much for most of us to deal with, whether as individuals or as governments. Issues and controversies are crossing national boundaries almost with impunity, making domestic legislation inadequate and some governments almost helpless. We can only address the situation if we act comprehensively and in a united fashion—united notwithstanding our differences, but respecting the cultural roots of those differences at the same time.

Some critics have taken UNESCO to task for providing in the Universal Declaration on Bioethics and Human Rights what they take to be generalizations that mean little in specific situations. To some extent, this may be true. But this can prove to be true only if governments, institutions and individuals were to wait for the Declaration, by itself, to make things happen. Unfortunately, the waiting game will get us nowhere. No Declaration, by itself, can accomplish anything.

The Declaration is a call for action and a specification of the earlier Universal Declaration on Human Rights to the field of bioethics. What UNESCO has provided in the Universal Declaration on Bioethics and Human Rights is a framework on the basis of which governments and institutions can structure their own responses to the problems and issues that are urgent and most relevant to them. Countries are at liberty to respond in a way and at a pace that is compatible with their specific circumstances. But, no matter
how they respond, they must start responding now and in harmony with the rest of the world.

The association of bioethics discourse with human rights signals the need for the greatest possible public involvement in deliberations on pertinent issues. To regard bioethics issues as human rights issues is to confer upon them a level of importance and seriousness that makes them everyone’s concern.

This level of seriousness ought to be pursued in a country such as the Philippines, where there has been a good amount of bioethics activity, but where the specific activities have largely been fragmented and sporadic – lacking in focus and begging for government support. In this regard, the application of bioethics to health research and organ transplantation provides concrete illustration. The passage of the Universal Declaration should be an occasion for government to institutionalize a sustainable response to issues of research ethics and organ transplantation by providing authorities with a legal basis for the exercise of review powers by ethics committees and their supervision by national bodies. It is timely also to organize a national bioethics commission to initiate and coordinate national initiatives in bioethics. The agenda for government and national bodies should include extensive efforts at bioethics education in its various areas, e.g. environmental ethics, agricultural ethics, etc. The efforts should include a well-coordinated information campaign directed at the grassroots.
**Abstract**

A successful implementation of international bioethics Declarations depends on concrete conditions of each country. These conditions in Vietnam are now rather specific. After many years of wars the country and nation concentrate their efforts on development of economy, improvement of education and health care. To do this effectively, among other things, the country should apply the achievements of modern science and technology, including biotechnology. In this social high speed development of economy, bioethical issues are sometimes considered as a ‘luxury’. This can explain several issues concerning bioethics, such as the lack of bioethics courses in most of schools; lack of some bioethical regulations; bioethics is not in the focus of public media and in public opinion in general.

In these circumstances some points in the Declarations may take time to be implemented. An example is Articles 8, 9 and 10 of the International Declaration on Human Genetic Data, concerning the very important issue of consent. Nowadays we do not have comprehensive official regulations on this matter and public as well as individuals, who give biological samples (genetic data) for hospitals or counselling, do not pay attention to the fate of their genetic information which will be obtained from the samples.

From the other side, in the abovementioned situation, some bioethics issues seem to be acceptable with difficulties. For example, all the measures, both direct and indirect, aiming at limiting abortion are useless, because we have an official Decree allowing free abortion, aiming at limiting the growth of population, a factor increasing poverty.
Another example is Article 3 of the Universal Declaration on bioethics and Human Rights, on human dignity and human rights, paragraph b: ‘The interests and welfare of the individual should have priority over the sole interest of science or society’. This principle in our conditions, at least at the moment is very difficult to be accepted.
Asia is the birthplace of all the major religions of the world. All religions believe in the existence of a Creator or Supreme Being. However, there are a variety of beliefs pertaining to the physical conception and birth of human beings. These beliefs include reincarnation and transmigration of the soul, of the survival of the soul after its corporeal death and a final day of judgment. I take this opportunity to summarise a present Pakistani viewpoint.

There are 57 countries of the world where a majority of the population practices the teachings of Islam. Approximately half of the countries of the Organization of Islamic Conference (OIC) are in Asia and Pakistan is one of these countries. Ethical issues in Islam are examined in the light of the teachings of the Holy Quran and the ‘Sunnah’ or the ‘traditions’ relating to the sayings and the way of life of the Holy Prophet Muhammad (PBUH). For Muslims these two are the fundamental guiding sources that give a complete code of life that includes economic, legal, social and ethical issues. It is noteworthy that Islam shares many fundamental values with Judaism and Christianity.

A third source of guidance is ‘Ijtihad’ or legislation by learned scholars, based on an earnest endeavour and knowledge of the circumstances of the day.

In Pakistan there is a National Commission for Bioethics under the aegis of the Ministry of Health and Centre of Biomedical Ethics and Culture at the Sindh Institute of Urology and Transplantation (SIUT), Karachi. Although there is no legislation to-date, the following subjects (in no particular order of importance) have been discussed extensively.
Abortion

Most Muslim jurists and religious scholars are of the view that although some form of life exists after conception, human life begins only after the ensoulement of the foetus. For this, guidance is sought from the Holy Quran:

We created man from a product of wet earth; then placed him as a drop in a safe lodging; then fashioned we the drop a clot, then fashioned we the clot a little lump, then fashioned we the little lump bones, then clothed the bones with flesh, and then produced it another creation. (The Holy Quran Surah, 23 : 12-14)

From several passages such as this, and traditions attributed to the Holy Prophet, Muslim scholars have inferred that from conception to birth, the fertilized egg passes through various stages in the womb and that the ‘spirit’ enters the human foetus after four months (120 days) of pregnancy. Before the ‘ensoulement’ of the foetus (40 days according to some scholars), abortion is permitted if there are reasonable juridical or medical reasons, which include rape. After 12-14 weeks of pregnancy, foetal cells can be obtained from the amniotic fluid or chorionic villi for genetic analysis of disease or abnormality of the foetus. Abortion after ensoulement is strictly forbidden. Further, the mother’s life takes precedence if there is a choice between saving the mother or the foetus.

In the present context, scholars agree that foetal tissue from legal abortions can be used for research in the larger interest of humanity.

Assisted reproduction (IVF), surrogate motherhood

Islamic scholars are in favour of in vitro fertilization (IVF), strictly for married couples with the agreement of both parties. This is usually the case if natural reproduction is not possible for any reason, or in case a married woman has to be treated for a disease that requires chemotherapeutic intervention or other procedures which can result in a miscarriage or severe abnormalities in the foetus. The ovum can only be fertilized with the husband’s sperm and at that time the husband must be alive.

The implantation of a fertilized ovum from a married couple into another woman’s womb (surrogate motherhood) is not permitted since according to Muslim law or Shariah, the legal mother would be the one who bears the child and not the donor of the ovum. Surrogate motherhood would also raise social and psychological problems for both the mothers and the child.
Genetic counselling and pre-implantation genetic analysis

Consanguineous marriages are permitted according to Islamic law and have been practised in most Muslim communities for more than fourteen hundred years. As a consequence, genetic abnormalities and disease causing genes often segregate in these families at a higher frequency than would occur in random mating. Therefore, genetic services and counselling are encouraged for both patient care and the prevention of disease. In case of IVF, pre-implantation genetic analysis is encouraged and if a genetic abnormality or disease is found, implantation is discouraged and avoided with the consent of the woman.

Gene therapy

With the completion of the sequence of the entire human genome, it has been estimated that it contains approximately 30,000 genes that carry all the information required to perform all bodily functions from conception to death.

Several thousand (healthy) genes have now been cloned. Gene therapy aims to replace a disease or defective gene with a healthy one to cure the disease. Although some success has been claimed in the laboratory, the procedure is not perfected yet but has great potential for curing diseases, specially those involving a single defective gene. Research to better understand this procedure is encouraged by Muslim scholars.

Cloning

Reproductive (human) cloning

During the natural process of reproduction, the child inherits genetic characters from both parents.

For reproductive cloning, the principle is to take a woman's ovum (egg) and remove its nucleus (DNA). A second nucleus, which has all the genetic information specific for producing an exact copy of another individual, the donor, is obtained from the somatic cell of the donor and transferred into the enucleated ovum (somatic cell nuclear transfer, SCNT). Procedures such as giving an electrical shock to this 'renucleated ovum' starts the process of making a 'cloned' embryo. This will contain the complete genetic information of only the donor, and not that of two parents. When implanted into a woman's uterus it possesses the possibility of giving birth to an offspring.
that would be identical to the person who donated the nucleus. To prevent ‘egg trade’ SCNT into an enucleated ovum is prohibited by Muslim scholars. The process of reproductive cloning produces an offspring that has the genetic characters of only a SINGLE individual, and not that of a combination of the TWO parents. This is considered unnatural in the light of verses of the Holy Quran. For example:

Glory be to Him who created all the sexual pairs, of which that the earth groweth and of themselves, and of that which they know not. (The Holy Quran, Surah 36: 36)

According to the Holy Bible (Luke 10:18) and the Holy Quran, the Devil (Satan) was expelled from heaven because of his pride (and disobedience), and he said:

Surely I will take of Thy bondmen an appointed portion, and surely I will lead them astray, and I will arouse desires in them, and I will command them, and they will cut the cattle’s ears, and surely I will command them and they will change God’s creation. (The Holy Quran, Surah 4:118-119)

In the light of this verse from Holy Quran, Muslim scholars are unanimous that human cloning is utterly and vehemently rejected (www.islamicinstitute.org) as it is tantamount to changing God’s creation because natural reproduction requires the union of the genetic material of a pair, a male and a female (The Holy Quran, Surah 51:49).

Many animals such as mice, rabbits, cats, pigs, sheep, calves, mules (sterile) have been cloned. Some important observations have been made:

- large offspring syndrome (LOS) presents problems for normal delivery.
- cloned animals show abnormalities. Dolly died of ‘old age’ symptoms etc.

These have to be seriously considered if human cloning is ever legalized.

**Therapeutic cloning**

Therapeutic cloning is a procedure that presents the possibility of producing an individual organ for transplantation into the same individual, thus circumventing problems of incompatibility and rejection. This is particularly promising in the use of adult stem cells (which are constantly produced in very part of the body to replenish and repair tissues) from the same individual that requires tissue or organ replacement (see below). Research in therapeutic cloning is permitted by some Islamic scholars.
**Transplantation**

Organ transplantation is practised in most Muslim countries. Generally, organs such as kidneys and liver are donated by living relatives. Cadaveric donations are also permitted by almost all scholars and the number of donations is increasing. In such cases the agreement of the donor’s relatives is mandatory. Sale of organs, specially kidneys, is undesirable but legislation is difficult. In the case of heart transplants, the consent of the donor’s family is required and is permitted only following ‘brain death’ (Third International Conference of Islamic Jurists, Amman, Jordan 1986; Council of Islamic Ideology, Pakistan).

**Stem cell research and therapy**

Research and applications of (embryonic) stem cells is perhaps the most controversial yet promising technologies of this age. It holds the promise of treating or curing such conditions as diabetes, Parkinson’s disease, Alzheimers disease, spinal cord injuries and paralysis, multiple sclerosis, heart disease and many other fatal diseases. Due to the nature of this work there are possibilities of serious abuses that present challenges to our ethical, moral and religious values. Embryonic stem cells (ESC) are nature’s ‘blank slates’. They are capable of dividing and renewing themselves for long periods. They can differentiate or be transformed to have specialized functions such as the insulin-producing cells of the pancreas or the beating cells of the heart.

Stem cell research is advancing our understanding of how an organism develops from a single cell and also how damaged cells are replaced in the adult. There are a number of sources for obtaining (embryonic) stem cells that possess the potential to differentiate into all kinds of cells, tissues and organs of the human body. These sources include oocytes, aborted foetus, blood, bone marrow, skin, etc. As described earlier, in vitro fertilization requires the fertilization of an ovum with a sperm (of the husband) to help couples, that are infertile for some reason or the other, to have children. Muslim scholars believe that this must be strictly for married couples and that at the time the procedure is done the husband and wife should be alive. The fertilized egg (embryo) is then implanted into the woman’s uterus to give birth to a child. This procedure requires that the ovaries of the woman are stimulated to produce several ova that are removed and usually, because of the low success rate, several embryos are produced per couple. Upon achieving a successful pregnancy following implantation of the embryo into the woman’s uterus, a very large number of the remaining embryo’s of that
couple are destroyed. Muslim scholars have concluded that based on the principle of ‘purposes of higher causes’, the spare embryos can be used for research under strict guidelines1. The renting of an ovum, sperm or uterus and any commercial use is strictly forbidden as is any effort to produce individuals with specified mental or physical characters. Although some success has been claimed in animal experiments for the repair of spinal cord injuries, heart muscle and vasculature and the treatment of diseases such as diabetes, the procedure is still in its infancy.

Adult stem cells that have already differentiated to become a particular tissue or organ are constantly produced to repair and replenish cells in different parts of the body. These cells are another source and are currently the subject of intense research.

Recent work on ‘Oocyte Generation in Adult Mammalian Ovaries by Putative Germ Cells in Bone Marrow and Peripheral Blood’ by Joshua Johnson and coworkers (Cell, Vol 122, 303-315, 2005) creates ethical problems. Do the oocytes (eggs) in a recipient female contain the genome of the donor? If fertilized, will the foetus have the genome of the donor or that of the recipient female?

**Ethical and scientific oversight**

Need for establishing an OVERSIGHT system at the national and institutional levels. (Embryonic Stem Cell Research Oversight - ESCRO committee) to assure:

1. Informed consent
2. Confidentiality, medical privacy protection
3. Human subjects protection for donors of somatic cells, oocytes and naturally aborted foetus
4. Laboratory standards and safety reviews of investigators
5. Animal care committee
6. Rules governing importation of biological materials, transfer of medical data to and from other countries.

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1. Islamic Law: [www.islamicinstitute.org](http://www.islamicinstitute.org)
CONTEMPORARY PROBLEMS OF BIOETHICS
AND ITS INTERNATIONALITY: AN ASIAN PARADIGM

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Abstract

Rapid spectacular advances in biology with their immense potentials for human welfare have simultaneously confronted humankind with complex ethical problems. While on one hand, the unraveling of human genome, advances in biotechnology and artificial reproductive technologies (ART) now enable us to battle against genetic and infectious diseases, engineer crops and livestock of desired quality and productivity, provide joy to infertile couple, these also pose complex ethical questions. The fear of revival of eugenics, cloning of human beings, the consequences of genetically modified organisms, the use of genetic tests for non-medical purposes, the concerns regarding ensuring confidentially of genetic data, the social and legal issue associated with ART confront the scientists and society alike. It is the recognition of these concerns that has led to the emergence of the discipline of bioethics.

The potential benefits offered by technological advances based on scientific research must be considered in the context of the associated social, legal and moral implications. It is to deal with such issues that has led to the establishment of national, regional and international bioethics committees.

The general principles of ethics may be universal as evidenced by the ongoing efforts of UNESCO through IBC, IGBC etc. to enunciate these. At the same time ethical principles and particularly their implementation is influenced by local culture, religious beliefs, the prevailing socio-economic conditions, even the political, administrative and legal structures. The nation
states in the Asian continent differ widely in these respects hence their perception of some of the ethical issues referred to earlier are bound to differ.

There are some common problems in most of these developing countries like poverty, illiteracy, lack of established mechanisms for ensuring public awareness and public debate on such issues, poor administrative structure to monitor and implement any guidelines or laws laid down. These have often been exploited by outsiders as observed in respect to biopiracy, experiments on human subjects or even for purposes of bioterrorism.

Similarly there are grave concerns regarding equity in respect to provision of nutrition and health care, commercial exploitation of poor and illiterate for organ transplantation. Some specific issues to be discussed are:

- In sharp contrast to the primacy of individual rights as prevalent in the Western world, the role played by the family and even socio-cultural groups in determining ethical norms and social values.
- The different views in respect to issues like defining beginning of life and status of embryos as also on issues related to end of life and active or passive euthanasia. Attempt will be made in this presentation to discuss some of these.