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INTERNATIONAL BIOETHICS COMMITTEE

TWELFTH SESSION, TOKYO, JAPAN

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UNESCO & UNIVERSAL PRINCIPLES IN BIOETHICS: WHAT'S NEXT?

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Michael Kirby*

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, the IBC addressed the future programme of UNESCO and of the IBC concerned with the universal principles of bioethics. This paper is a contribution to that consideration.

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1 SHS/EST/05/CONF.204/3 REV (24 June 2005).

2. In order to discuss "What's Next?", it is necessary to understand where the 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[2], 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[3]. Under the leadership of the President of the IBC (Mme Michèle 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

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2 The process was initiated by a seminal paper prepared by two IBC members, Professors L de Castro and G Berlinguer, "Report of the IBC on the Possibility of Elaborating a Universal Instrument on Bioethics" (SHS/EST/02/IBC-9/5, June 2003). The adoption of this report led to a communication to the Director-General of UNESCO (32C/59, 22 September 2003). The first meeting of the IBC drafting Group was held on 30 April 2004 after an Extraordinary Session of the IBC 27-29 April 2004 during which some intergovernmental bodies, NGOs and national ethics committees were consulted.

3 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.

formed the basis of inter-governmental consultations. These consultations that 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 the IBC. The variations which were introduced before the craft of that 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 Inter-Governmental Bioethics Committee (IGBC), a review by invited experts and intensive debate in the two sessions of an Inter-Governmental Meeting of Experts aimed at finalising the draft Declaration. The second such meeting took place 20-24 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 Inter-Governmental Meeting of Experts and appending a revised text, described as a "consensus document", which was transmitted to the

Director-General[4]. It is this revised text which was submitted to the General Conference and adopted.

6. A comparison of the draft Declaration completed by the IBC and the final text approved by the Inter-Governmental experts indicates two things:

6.1 The overall structure and contents of the Declaration was unmistakably similar to the document prepared by the IBC; but

6.2 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 the IBC.

7. It is not the purpose of this paper to provide a close textual comparison between the IBC draft and the Inter-Governmental Experts' draft. No doubt that comparison will be performed elsewhere. It is sufficient to notice that the main lines of the variations between the two drafts were as follows:

7.1 Minor alterations to the Preamble;

7.2 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;

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[4] SHS/EST/05/CONF.204/6.

7.3 Alterations to the expression, content and order of the Principles recommended by the 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";

7.4 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 to "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). The 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 the 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;

7.5 The list of procedural "Principles" included in the IBC draft (esp 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;

7.6 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".

7.7 The IBC proposed machinery for monitoring and evaluating the implementation of the Declaration through the 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

7.8 The recommended title of the 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, the IBC. As will appear, one issue presented by the foregoing developments concerns the appropriate inter-relationship between an expert advisory body, such as the IBC, and the Member States of UNESCO, advised by an Inter-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 the 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 Art 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 the Member States of UNESCO must necessarily have the last word. Whilst some Members of the 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 the IBC have survived, in one form or another, in the present text[5]

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[5] 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) become new Art 4;

Footnote continues

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:

11.1 The 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.

11.2 Similarly, the innovative inclusion in the IBC draft of former Art 15 (Responsibility towards the Biosphere) is preserved, in its essence, in the new Art 17 (Protection

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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).

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.

12. Most especially, the present text preserves the insistence of the 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[6]. 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 the IBC and UNESCO. It will retain most of the essential concepts of the IBC draft. It will

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[6] Adopted and proclaimed by the United Nations General Assembly Resolution 217A(iii) of 10 December 1948.

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 the 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?".

14.1 First, it is necessary for the 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;

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

14.3 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.

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 the 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 the 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 the 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 the 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, member of the IBC, USA) 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 organisations 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 the 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 the 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 the 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, the IBC should rise to it.

28. *Explanatory texts:* An Explanatory Memorandum was prepared by the IBC, based on its own text[7]. 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

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[7] The Intergovernmental Meeting of Experts did not agree to the Explanatory Memorandum prepared by the 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)).

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 the IBC, the IGBC and the Inter-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 the IBC and the 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.

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:

33.1 Respect for Human Vulnerability and Personal Integrity (Art 8);

33.2 Cultural Diversity and Pluralism (Art 12);

33.3 Social Responsibility and Health (Art 14);

33.4 Protecting Future Generations (Art 16); and

33.5 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 the 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 the 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. The 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 the 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 the IBC, with fresh stimulus from the new Universal Declaration. These topics include:

36.1 Issues of intellectual property;
36.2 The risks of transgenesis;
36.3 The bioethics of poverty;
36.4 Feminist perspectives of bioethics;

36.5 Animal experiments and respect for animal life;

36.6 Global climate change and bioethics;

36.7 Bioethical issues for outer-space; and

36.8 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 the IBC that need to be considered both by the IBC and, more generally, by UNESCO and the Director-General.

39. The entitlement of the 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 consideration 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:

40.1 The time allocated to the preparation of the Declaration was, in retrospect, somewhat too optimistic given the novelty, complexity and disputability of the issues;

40.2 The time for governmental consideration, both domestically and at UNESCO, was severely curtailed because of the Organisation's timetable, fixed by the timing of the General Conference;

40.3 Several of the issues raised in the IGBC could be explained by Members of the 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 Inter-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 the 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;

40.4 There remain some difficulties perceived in the language preferred by the Inter-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;

40.5 The foregoing suggests that an improved procedure is required, in any future activities involving the IBC and Inter-Governmental Experts, so that recommendations and difficulties are fully communicated, understood and taken into account before final texts are settled;

40.6 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. The IBC necessarily must respect the decisions of Member States. However, some concern has been expressed that the Inter-Governmental Experts were not always aware of the reasoning and discussions within the 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 the 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 the 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 the 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. The 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 the IBC and UNESCO can learn from the institutional experience derived from the preparation of the Declaration. Some points of difference between the 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 Inter-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 the 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 the 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 the 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 the 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 the 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. The members of the IBC also have a duty to

consider further issues and to assist the IBC to maintain its place as an intellectual leader in the field of bioethics and a significant actor in the global community.

Canberra, Australia
14 December 2005