

**THE AUSTRALIAN INSTITUTE OF INTERNATIONAL AFFAIRS
NEW SOUTH WALES**

2005 CHARTERIS LECTURE

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**THE UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN
RIGHTS - PRESENT AT THE CREATION^{*}**

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REMEMBERING A H CHARTERIS

As one grows older, and approaches the great void, the lives of influential predecessors become more interesting. Archibald Hamilton Charteris is no exception. He was Challis Professor of International Law at the University of Sydney from 1920 to his death in 1940. He helped to put international law on the map in Australia. By broadcasts to the public and lectures to the small but influential band of students of the Sydney Law School, he conjured up a vision of a world in which law, not

^{*} This text draws on a joint article written by Professor Henk ten Have (Head of Secretariat IBC, Mme Michèle Jean (President of the IBC) and the author (who was chairperson of the IBC drafting group preparing the Declaration described herein.

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just military power and financial capital, would govern the relationships of nations and peoples¹.

Charteris was born into a distinguished academic family in Scotland. He left his homeland for Australia in 1920. In Scotland he was an active council member of the International Law Association and participated in the activities of Royal Institute of International Affairs. His service in the First World War, his involvement in international conferences and his frequent radio broadcasts made him an engaging and well known character.

Charteris intrigued Australians by his "ringside view" of how the rules of international law were developed and how they were applied². In this lecture, that honours his name, I plan to follow his precedent. I will offer a ringside view on the development of a new international instrument - the *Universal Declaration on Bioethics and Human Rights* of UNESCO.

Charteris was described as a "menace" because he read everything. He realised, and taught, that, in international relations and law, the devil is usually in the detail. He was notoriously unconcerned

¹ J G Starke, Entry on Charteris in *Australian Dictionary of Biography*, Vol 7, 619.

² W S Sheldon, "Professor Charteris" in Sir Thomas Bavin (ed) *The Jubilee Book of the Law School of the University of Sydney 1890-1940* (Sydney, 1940), 38 at 39.

with dress. But he was called by a student who honoured him "almost the only loveable [man] who is not a bore"³. In Sydney, indeed Australia, we have been blessed with a succession of fine teachers of international law. Almost without exception, they have communicated their discipline to the general public. The public realises that the future of our species is dependent, in a direct way, upon the strengthening of the institutions of international law. To that end, like Charteris, I have sought to contribute wherever I properly can.

I thank the Institute for honouring the contribution of A H Charteris. For the inscription to his cartoon in the Jubilee Book of the Sydney Law School, he chose a text from Shakespeare's Henry VIII: "When I am forgotten - say I taught thee". By this lecture, we remain true to his injunction. We honour him and all teachers of international law.

THE UNIVERSAL DECLARATION ON BIOETHICS

Adoption of the Declaration: At the thirty-third General Conference of the United Nations Educational, Scientific and Cultural Organisation (UNESCO), convened in Paris on 19 October 2005, the Member States adopted the *Universal Declaration on Bioethics and Human Rights*.

³ Sheldon, *ibid*, 44.

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This instrument is not, as such, part of international law. It is not written in the form of a treaty. The Member States of UNESCO are not invited to subscribe to or ratify it. They do not bind themselves to comply with its terms. Its language is, in any case, expressed at a high level of generality and aspiration. But it is the first international endeavour to state the general principles intended to apply generally to bioethical decisions or practices. In this sense, the Declaration constitutes the first attempt of the organised international community to address one of the most perplexing and important issues of our time. I refer to how the myriad of decisions and practices, made or carried out by States, corporations and individuals, having biotechnical implications, will conform to the basic expectations of humanity.

We live in an age when remarkable developments of biological science, married to the technology of informatics, present prospects of extraordinary changes in medical therapies, in our awareness of disease and its causes and our capacity to treat and cure illness. The outcome of the Human Genome Project provides the present generation of humanity with knowledge of the entire genome of our species. This promises potential modification of genes in ways that could truly alter features of humanity that have existed for millennia. Suddenly, we are armed with great scientific knowledge and with technology that can render that knowledge a boon or a burden to future generations. It is this challenge that prompted the initiative of UNESCO to prepare a Declaration, for adoption by the Member States, that would express the

fundamental principles to be observed in the pursuit of the science and in the advance of the new discoveries of technology.

The International Bioethics Committee: Since 1997 I have served as a member of the International Bioethics Committee (IBC) of UNESCO. This body, comprises about 45 persons from different countries, disciplines, cultures and skills. It has been in the forefront of the development of the response of the United Nations to the foregoing scientific changes. In 1997, IBC adopted the *Universal Declaration on the Human Genome and Human Rights*. In 2002, it began explorations of the possibility of formulating general norms on bioethics. Having accepted the mandate of the Director-General (Mr Koichiro Matsuura) to attempt to draft an international instrument on this topic, the IBC, under its Chairperson, Madame Michèle Stanton-Jean (Canada) appointed me to chair the Drafting Group that would prepare the proposed Declaration. This I did at a series of meetings that took place in Paris in 2004-2005. The outcome of those consultations was the *Universal Declaration* that has now been adopted by the General Conference of UNESCO.

Text of the Declaration: The Declaration follows the general format of the earlier Universal Declaration and other like instruments of UNESCO. There is a lengthy Preamble, with reference to the many relevant instruments developed under the auspices of the United Nations and by other bodies including those in the field of medical and biomedical science. Some general provisions state the scope and aims of the Declaration. There follows the core of the Declaration, comprising

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the Principles which the Declaration puts before the international community in order to guide "decisions or practices taken or carried out by those to whom it is addressed". Such Principles "are to be respected". There follow sections dealing with "Application of the Principles" and "Promotion of the Declaration" with some final provisions concerned with matters of interpretation.

It is not the point of this lecture to repeat the text of the Declaration. I shall annex the "Principles" for they constitute the most important part of the document. Its overall purpose is to bring together the developments that have occurred in the fields of human rights and bioethics. Substantially, human rights have, in recent times, been expressed by the organs of the United Nations and developed as part of international law. Bioethics, on the other hand, has a much longer history. In all civilisations it can be traced to ancient times. In Western Europe, it can be traced to the teachings of the Hippocratic Oath in Ancient Greece. A main purpose of the new Declaration is to bring together these two streams of moral authority. That is why, in the Principles, one can see expressed concepts that have been derived from each of the two streams.

Article 3 demands full respect for human dignity, human rights and fundamental freedoms. Article 4 calls for the maximisation of benefits to patients, research participants and others and minimisation of possible harm to such individuals. Article 5 expresses the need for respect for the autonomy of all persons to make decisions affecting themselves.

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Article 6 enshrines the principle of prior, free and informed consent. Article 7 addresses the particular problems that arise where special protection is needed for persons who do not have the capacity to consent. Article 8 demands respect for human vulnerability and for the personal integrity of individuals and groups with special vulnerability. Article 9 upholds the concepts of privacy and confidentiality. Article 10 expresses the fundamental equality of human beings and demands that they be treated justly and equitably. Article 11 establishes the rule of non-discrimination and non-stigmatisation.

There then follow a series of more general Articles not addressed, as such, to the individual but to society, States and the global community.

Article 12 is concerned with respect for cultural diversity and pluralism. However, these values are not to be invoked so as to infringe human dignity, human rights and fundamental freedoms or the other Principles set out in the Declaration. Article 13 upholds solidarity and cooperation in the international community. Article 14 is an innovative provision demanding that the promotion of health and social development is a central purpose of humanity so that decisions and practices having bioethical relevance are expected to take into consideration the need to improve access to quality healthcare, access to adequate nutrition and water, improvement in living conditions and the environment, elimination of marginalisation and exclusion and the

reduction of poverty and illiteracy. Without these social developments, bioethical choices will often be hollow⁴.

Article 15 upholds the sharing of benefits of biomedical advances. Article 16 demands the protection of future generations. Article 17 requires due regard to be given to the inter-connection between human beings and other forms of life together with recognition of the importance of access to 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.

BUILDING CONSENSUS ON INTERNATIONAL BIOETHICS

Building blocks of the era: I now want to say something about the way in which the Declaration was developed. It is an interesting story and provides an illustration of the manner in which the building blocks of the new era are created to govern the way human beings live together in peace and harmony.

In October 2001, the General Conference of UNESCO, supported by the Round Table of Ministers of Science, invited the Director-General of UNESCO to examine the possibility of developing a universal

⁴ T Faunce, "The UNESCO Bioethics Declaration 'Social responsibility' principle and cost-effectiveness price evaluations for essential medicines" (2005) 24 *Monash Bioethics Review* 10.

instrument on bioethics. The feasibility study drafted by the IBC concluded that it was possible to find common ground in divergent bioethical positions by focusing on basic principles. Some of these principles had already been identified in previous declarations. The study also stressed the necessity to develop a universal instrument because scientific practices are now developing rapidly and extending beyond national borders. Developed and developing countries should therefore achieve broad consistency in regulations and policies.

In October 2003, the General Conference considered that it was desirable to set universal standards in the field of bioethics. It provided a mandate to submit a draft declaration in two years. In the meeting, the French President (Mr J Chirac) made a vigorous plea for a universal normative framework, preferably a Convention, to guide the progress of the life sciences and to protect the integrity and dignity of human beings.

The elaboration of the text was entrusted to the IBC, as the only existing global body of experts in bioethics. The subsequent process of drafting, taking into account the short time frame, the enormous variety of ethical cultures and traditions, and the controversial nature of many bioethical issues, had four characteristics.

Gradual elaboration: To explore ideas about the scope and the structure, all Member States were consulted in writing between January and March 2004. The IBC organized a meeting in April 2004, inviting Intergovernmental Organizations (e.g. FAO, WIPO, Council of Europe),

NGOs (e.g. WMA, HUGO), National Bioethics Committees (e.g. from Japan, Korea, New Zealand, Mexico, Republic of Congo) and international bioethics societies. Questions debated at this stage included whether the focus should be on human beings or broader; which fundamental bioethical principles could be identified; and whether specific areas of application of the principles should be explored.

Extensive consultations: Drafting the text between April 2004 and January 2005, the IBC extensively consulted many stakeholders. The UN Inter-Agency Committee on Bioethics (UNESCO with FAO, WHO, OESO, WTO) discussed drafts during two of its meetings. Consultations with regional experts took place in Buenos Aires, Argentina and Moscow. National consultations were held in the Netherlands, Iran, Lithuania, Turkey, Korea, Mexico, Indonesia and Portugal. In August 2004, the IBC organized a public hearing in Paris, inviting representatives of different religious and spiritual perspectives. Finally, the draft text was subjected to a written consultation with all Member States between October to December 2004. In addition to providing a very interesting forum for the discussion of the future Declaration, the meetings in different countries raised awareness about the work of the UNESCO in ethics and bioethics. They also provided an opportunity to meet with ministers having various governmental responsibilities.

Transparent process: During the elaboration of the text, drafts, at various stages of the elaboration process, were published on the website of UNESCO. The work of the IBC drafting group was therefore

conducted in as public a way as possible in order to facilitate consensus formation and early identification of any dissenting views. During the 2005 General Conference many member states recognized and praised the quality of the consultation process put in place for the elaboration of the Declaration.

Multiple expertise: Dealing with bioethics in an intergovernmental organization such as UNESCO implies a linkage between science and politics. Any normative instrument needs to reflect the scientific and ethical state of the art. But in the end it is submitted for approval to the Member States which then decide if they want to adopt it. The draft text developed by independent scientific experts of the IBC was necessarily subjected to political negotiations amongst the governmental experts who represented the governments of Member States. The result is that the cogency of the final text, in some respects, may be diminished in order to create maximum adherence by all of the governments involved. In order to facilitate the opportunities for compromise, the work of the independent IBC was connected at an early stage with that of governmental experts. Several amendments to the IBC text were made by the governmental experts. The Declaration, as adopted, represents the IBC draft as so amended.

IMPLICATIONS AND IMPACT

Bioethical problems commonly arise because conflicts exist between several competing ethical principles. Sometimes it is not

obvious which principle is to prevail. Accordingly, a careful balancing of principles is usually required. The new Declaration states principles that may occasionally seem inconsistent. However, ethical decision-making in practice frequently requires rational argumentation and the weighing of the principles at stake. In order to advance decision-making, the principles are to be understood as complementary and interrelated (Art.26).

It is significant that all 191 Member States of UNESCO were able to agree upon the relevant bioethical principles. The Declaration, although a non-binding legal instrument is therefore the first international document in bioethics adopted by all governments. Other very influential documents have been adopted by non-governmental organizations (eg the Declaration of Helsinki). However, generally, these do not create the same commitment on the part of governments. It has also been pointed out that the Declaration's grounding of bioethics in universal human rights will bring international bioethics into a new phase of involvement with regulation and implementation, being accepted as part of international law. Eventually it may be expected that the new Declaration will become the starting point for an international bioethics convention.

It is very important to say that the text of the new Declaration is the beginning rather than the end of a process of internationalization of bioethics. Special attention therefore needs to be given to the application of the principles and the dissemination and the promotion of the

Declaration. Member States that have not already done so will be encouraged to establish bioethics committees; to promote informed pluralistic public debate; to foster bioethics education and training; and to take appropriate legal measures to facilitate transnational research. International organizations such as UNESCO will continue to assist countries to develop an ethical infrastructure so that human beings everywhere can benefit from the advances of science and technology within a framework of respect for human rights and fundamental freedoms.

I am sure that you will appreciate the privilege that it was for me to be the chairperson of the highly talented group that drew up the Universal Declaration on Bioethics. I had the assistance of consultations with an interdepartmental committee of Australian experts assembled by the Australian Department of Foreign Affairs. That Committee respected my independent position in the IBC. I respected the Committee's duty to give its independent advice to the Australian Government. However, it was a constructive relationship.

Now that the Declaration has been adopted, consideration has to be given to promoting knowledge about its terms and securing its implementation and use throughout the world. This is the subject of a session of the IBC to take place in Tokyo, Japan in December 2005. I have prepared a paper "What's Next?" for that session which will be my last as a member of the IBC. It has been a privilege to take part in the work of the IBC and especially as chair of the drafting group of the new

Universal Declaration on Bioethics and Human Rights. Truly its concerns affect the future of humanity. They deserve widespread study, intensive reflection and effective follow-up.

ANNEX

UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS – PRINCIPLES

ARTICLE 3 – HUMAN DIGNITY AND HUMAN RIGHTS

Human dignity, human rights and fundamental freedoms are to be fully respected.

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

a) 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.

b) 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 the modalities for withdrawal of consent. The 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.

c) 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:

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

ARTICLE 8 – RESPECT FOR HUMAN VULNERABILITY AND PERSONAL INTEGRITY

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

ARTICLE 9 – PRIVACY AND CONFIDENTIALITY

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

ARTICLE 10 – EQUALITY, JUSTICE AND EQUITY

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

ARTICLE 11 – NON-DISCRIMINATION AND NON-STIGMATIZATION

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

ARTICLE 12 – RESPECT FOR CULTURAL DIVERSITY AND PLURALISM

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

ARTICLE 13 – SOLIDARITY AND COOPERATION

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

ARTICLE 14 – SOCIAL RESPONSIBILITY AND HEALTH

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

ARTICLE 15 – SHARING OF BENEFITS

- a) 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:
- (i) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
 - (ii) access to quality health care;
 - (iii) provision of new diagnostic and therapeutic modalities or products stemming from research;
 - (iv) support for health services;
 - (v) access to scientific and technological knowledge;
 - (vi) capacity-building facilities for research purposes; and
 - (vii) other forms of benefit consistent with the principles set out in this Declaration.
- b) 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 the respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity

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