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THE UNIVERSITY OF SOUTHERN QUEENSLAND

TENTH CONCANNON ORATION 1997

TOOWOOMBA, QUEENSLAND 17 SEPTEMBER 1997

THE CHALLENGE OF THE GENOME

The Hon Justice Michael Kirby AC CMG

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> "Our future is not written. The human condition is incompatible with certainty"[1]

HUMAN GENOME PROJECT & GLOBAL CHALLENGES

I am proud to be invited to deliver the Tenth Concannon Oration. As the schedule of the previous Orations reveals, it is an important event in the life of this university community and of the city and district which nurtures it. It is also a generous contribution by Concannon College to the academic life of the

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* Justice of the High Court of Australia. President of the International Commission of Jurists. Member of the UNESCO International Bioethics Committee. Member of the ethics Committee of the Human Genome Organisation.

[1] Primo Levi.

University. Specifically, it is a contribution by the Church which established the College to be a centre of residence and, more importantly, a centre of scholarship in which secular and religious students could work and live in dialogue with each other. The object of this noble cause reflects an initiative of the Church which finds parallels in the founding of the first European universities in medieval times. Those universities were established on the basis of the proposition:

> "Truth cannot contradict itself. The pursuit of truth, whether it be secular or religious, will lead to an harmonious growth of humanity itself".

I want to talk about a development in the pursuit of truth which must engage secular and religious scholars everywhere. It must engage town and gown. It must engage the churches but also those who have no spiritual beliefs. It concerns humanity itself. Indeed, in potential, it concerns the very definition of what humanity is or what it may become.

Life today is extremely exciting in the new intellectual challenges which science and technology present to us. As a result of work I did in the 1970s in the OECD on privacy, suddenly I became aware of the international institutions which develop the law. I have been afforded all kinds of opportunities to do things on international committees and commissions. It is in this way that I came to know the remarkable genome.

One of the things I was asked to do on my way to the genome was to join the World Health Organisation Global Commission on AIDS. This was extremely interesting and, of course, very important. Another, was to join the work of the United Nations' Development Programme in Malawi and in Lesotho. Another was to take part in the International Labour Organisation mission to South Africa just before the change of government. That was the reason that I received an invitation to President Mandela's inauguration on a beautiful blue day in Pretoria.

However, the matters that I want to talk about tonight relate to two other international committees which I have joined relevant to the genome. One of them is the Ethics Committee of HUGO (the Human Genome Organisation). HUGO and its committee used to be based in Bethesda which is near Washington in the United States. It is now based in London. The second is the International Bioethics Committee of UNESCO. That body is based at UNESCO Headquarters in Paris. These are the two international bodies, HUGO and the International Bioethics Committee, which are striving to develop the international response to the greatest cooperative scientific programme in history: the Human Genome Project.

The Human Genome Project was launched in 1988. In fact, for about a decade before that there had been cooperation between scientists involved in genomic research. The Project represents the amalgamation of two of the great scientific developments of our time. There is a symbiosis between the two. Biology and genetics, on the one hand, and informatics, on the other. You could not have had the Human Genome Project and genomic sequencing without informatics. Therefore, the two technologies are coming together in a merger which is extremely interesting, important, very promising but, as always in such matters, carrying various risks and presenting various problems.

The International Bioethics Committee of UNESCO is preparing what is called a Preliminary Draft for an *International Declaration on the Universal Rights in Relation to the Human Genome*. The Ethics Committee of HUGO works in a rather ill-funded way, giving advice to the Council of the Human Genome Organisation on various ethical questions which arise from time to time and which are either referred to it by the Council of HUGO or which originate within the Ethics Committee itself. Inevitably, as these things happen, there is an overlap between the personnel of the two Committees. The Chair of the HUGO Committee, Professor Bartha Knoppers of Montreal, is also, like me, a member of the International Bioethics Committee of UNESCO.

The present draft of the *Universal Declaration* which is being prepared for UNESCO should be taken seriously because, if you look at international law and the way it develops, often the first step is an international declaration. This is what happened with the *Universal Declaration on Human Rights* in 1948. That instrument led on, in due course, to the *International Covenant on Civil and Political Rights.* The *Declaration* is a broad statement of international principle. The *Covenant* is a binding treaty which gives rise to legal obligations and to machinery provisions for its enforcement.

So it is in the area of genomic research, genomic issues and bioethical questions concerning the genome. One subset of the issues which the Human Genome Project throws up is that of privacy - and I want to speak with particular reference to that topic. The *Universal Declaration* is being prepared. We have to take it seriously because it may, in the way these things happen, go on in due course to become an international treaty to which countries like our own will subscribe. At that stage it would become part of the binding international law. So it deserves serious and close attention to ensure that the regulatory principles are right and acceptable to our values in Australia and as human beings.

THE MEDICAL ENCYCLOPAEDIA FOR A MILLENNIUM

Just a few words about the Human Genome Project itself, because we have to get some understanding of what is happening. Do not forget that it arises out of the human mind. It is not something other, separate from us. It is part of us but we did not know of its miraculous features until less than fifty years ago. In 1953 the scientists Watson and Crick visualised in their own minds what DNA looked like, the famous double helix: the building blocks of biological existence. On the double helix are about a hundred thousand genes of the human species. The human genes are divided. They can be sequenced. Putting it at a very basic level (which is about the only level that I really understand) on the "markers" that are being sequenced are the indications, ie the programme determining whether you will be tall or short, whether you will have blue eyes or brown eyes or hazel eyes, whether you will go on to obesity, whether you will develop Alzheimer's or Huntington's disease, whether you will develop the various dramatic, and sometimes fatal, human conditions of illness. All of these biologically determined conditions are there in the sequences. The purpose of the Human Genome Project is, in essence, to link scientists on every continent. In practical terms that basically means scientists in Japan, North America, Europe, Australia, New Zealand - speaking to each other - sharing their research. By linking them the scientists hope to find where the "markers" are for the multitude of diseases and human characteristics such as I have mentioned. The Human Genome Project will therefore become the encyclopaedia of medicine for the next century. It is therefore extremely important that the mapping be done accurately. It is vital that it should be done quickly (the programme is spaced over a period of 20 years). The purpose is, within that 20 years, to try to find all of the markers and to identify them and then to provide for what is to happen to them.

Obviously, I am talking about mega-bucks here. If you can identify the marker for, say, baldness, and if you can find where that is on the genome, then the next step is to try to programme out (either in the individual affected or in the germline of that individual for future generations) the condition of baldness in that family. Similarly with Alzheimer's disease, Huntington's, Parkinsons and likewise with the other diseases of a genetic character. Obviously the potential for human good and for the relief of pain and suffering, distress and anxiety is enormous.

LEGAL PROBLEMS & THE GENOME

A number of complex problems are presented. Many of them are of a legal character. Many of them are of an ethical character. Amongst the legal and ethical questions will be those presented in the criminal field. Take the concept of free will, which is the foundation of criminal law and the hypothesis upon which its prerequisite *mens rea* is built. Is this something which will withstand a full understanding of the genome? Can we talk honestly about criminal intent in the case of a person with a demonstrated genetic propensity to violence? If we find that some people are simply acting out their genetic messages in terms of violence, is it then just and principled, is it in accordance with the principles of the foundations of our criminal justice system, simply to deal with such persons as if they have *wilfully* done something?

Another area of the law that is affected is intellectual property. The National Institutes of Health in the United States made many applications for patenting the sequences upon which the "markers" would be found which they suspected might be relevant to particular genetic conditions and have a large economic potential. The sequences themselves were the subject of applications to the United States Patents and Trademarks Office in Washington. That action led to a tremendous controversy in the developing world whose leaders attacked it as an attempt by one country to get effective control of something that actually belonged to all humanity. However, there was also an outcry within the United States itself. Scientists pointed out that Watson and Crick had never sought to make a single cent out of their great discovery. Opponents of patenting urged that science should belong to everybody. The genome should not be "owned" in intellectual property terms by any particular person or group.

In the latest issue of *Science* magazine to reach Australia[2], it is reported that the US National Academy of Sciences has

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[2] *Science*, vol 277, 4 July 1997.

appealed to the US Patent Office expressing concern at the willingness to grant patents on mere fragments of human genes - particularly those known as expressed sequence tags (ESTs), which can be used to identify full-length genes. ESTs are relatively easy to capture but reveal little about the biology they control. The Academy has expressed fears that patenting ESTs - a few have been patented and thousands are pending - could create a tangled maze of property rights and impede research. The Academy begged that patents be reserved to cases where immediate "real world" applications are described or detailed information about the operations of the gene are supplied. For some people even this would be taking legal controls too far. Yet the Patent Office says that it will just go on applying the legislation until a court says otherwise or Congress changes the law.

I try to talk to colleagues - judges and lawyers - about these issues. After a short time their eyes glaze over because this is all just too complicated. It is just too daunting. But it is important that universities and churches, which are committed to fundamental human rights and specifically to the defence of privacy and human dignity, should consider what are the implications of this the greatest scientific cooperative endeavour in history. Certainly, the Human Genome Project is bigger by far than the Manhattan Project. In some ways it presents analogies to the way in which science rushed into nuclear weaponry without really fully conceiving, and thinking through, the consequences for humanity. That is what HUGO and the International Bioethics Committee of UNESCO are trying to do: to stand back and look at these developments for the purposes of getting our fundamental principles and approaches right.

THE ISSUES OF PRIVACY & CONFIDENTIALITY

Two documents have addressed the particular issues of privacy and confidentiality in the context of genetic research which I now want to address[3]. They are (a) the Draft of the *International Universal Declaration* and (b) a paper by Professor Bartha Knoppers[4] which relates to the privacy and confidentiality issues of the Human Genome Project. I want to tell you the substance of what Professor Knoppers says because in some ways the issues of privacy and confidentiality are more concrete and manageable. We can comprehend them. We can see in them a microcosm of the complex ethical and legal issues which our encounter with the genome raises.

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[3] (1996) 3(2) *Genome Digest* at 3.

[4] B N Knoppers, "Privacy, Confidentiality and Genetic Information", as yet unpublished paper for the UNESCO International Bioethics Committee (1997).

Professor Knoppers starts with an acknowledgment that, in the business of protecting privacy and confidentiality in the context of the genome, we begin with the *Universal Declaration* and the *International Covenant.* This is not just a vague and nebulous claim. It is something which international law provides for, namely the defence and protection of individual privacy. That is a foundation that we begin with.

However, the point of Professor Knoppers' paper is to bring out some of the problems in terms of respecting privacy with the advance of genomic research and with the development of our understanding of the human genome.

The paper puts to one side the mighty questions that will have to be answered. One of these is the following. If you can get the "markers" and identify the characteristics and begin to programme this in and that out, do you render the next generation, which is programmed in this way, specially susceptible to disease and infection? One of the defences of humanity against epidemics has been the diversity of the gene pool. If you were able to programme out that diversity would we render humanity much more susceptible to infection? This is, in a sense, the biggest question. Is the moment in human history through which we are living one which will be looked back on, in the end of the next millennium, as the time when the human species conceived the possibility of creating from itself, effectively, a new species? It is at least possible. In science you should always think far ahead. We all know from the field of informatics and privacy that things which were unthinkable twenty years ago have a tendency to come to pass. So it will be with genomic research. If you can create a super pig or a super cow, may it just not be possible that someone, somewhere will conceive the notion of a super human being? Are we going to be seen as the generation which began the process of creating a new super human species? Is this possible: Is it desirable?

I put these enormous dilemmas to one side. They are too difficult. Let me come back to the much more homely and comfortable area of genome privacy. At least there we have some conceptions about the notion of privacy and how we can tackle it.

Professor Knoppers divides her representation of this issue into subsets of the subtopics of genomic privacy in the context of genetic privacy. She refers to the background work of the Canadian Privacy Commissioner, the Australian Privacy Commissioner, Mr O'Connor's paper on genetic privacy[5] and also the work of the New Zealand Privacy Commissioner. She then

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[5] Australian Human Rights and Equal Opportunity Commission, Privacy Commissioner, *The Privacy Implications of Genetic Testing,* Information Paper No 5 (1996).

goes on to say that we have to conceptualise this topic under the following headings: the consequences for the data subject, for the patient. The consequences for the family of the subject. The consequences for third parties, specifically employers and insurers. The consequences for researchers. The consequences for the State. They are the six subtopics which give a concrete focus to a very practical issue presented by the genome.

So far as the *subject* is concerned, the general principle of medical confidentiality goes back to ancient times. The *Hippocratic Oath* contained a promise on the part of the health worker not to reveal the secrets of a patient found in the healthcare relationship. This is absolutely basic. But a new feature which comes along with the developments of the Human Genome Project and of burgeoning genetic information is this. There may be some data which the data subject does not want to know. If you had the possibility of knowing, in your youth, what the basic course of your entire medical history was going to be, you might elect not to know it. You might prefer not to be subjected to the tests which would reveal it. You might insist that this is information that you just do not want to have. So a new component is brought into this area in terms of defending the right of the data subject *not* to have information given to themselves. Do you agree with that? Is there a right *not* to know? This is a new twist because until now, with a demand for freedom of information and for access to medical files the issue has generally been one of the right of the subject to know. Now it may be *not* to know.

In terms of the *family*, Professor Knoppers points out that until now, in terms of medical information, the family have just been treated as members of the group called "third parties". In other words, a family was undistinguishable from a neighbour or anybody else. You do not give the health information of the individual to the family except, of course, in the case of dependent persons, such as children or incompetent people. Generally speaking, it is not the right of your family to have access to your health data without your fully informed consent. But in the case of genetic information a new problem is presented.

Everybody in a genetic relationship with the data subject may have some concern or interest in the information which is not specific and limited to the data subject. That information may be of high relevance to the members of the genetic family. A question is then presented which bears some analogy to problems that have been faced by the law in fields such as psychiatric disturbance or in fields such as HIV/AIDS sero status. What circumstances will authorise the giving of data which is of relevance to a family for genetic purposes (genetic information) although the data subject *refuses* to allow the data to be given voluntarily? In what circumstances should we over-ride the denial by the data subject to give consent so as to permit a family member to have access to such data?

A Presidential Commission in the United States laid down four suggested criteria for over-riding the wishes of the data subject on such a matter. One of the questions before us is whether they are appropriate conditions. The *Tarisoff*[6] case in the United States was a case concerning the problem of a psychiatrist presented with information which causes the psychiatrist to be alarmed at the possibility that his patient might commit a very serious crime - as he did. When is a psychiatrist in such a position required or authorise by the common law, by the higher calling of society, to give that information to law enforcement officers or to others? Against the possibility that once or twice or on a few occasions that knowledge might help prevent a crime, is it warranted to authorise the provision of such information to third parties? Is it warranted to do so only on the basis of suspicion? Some people are extremely suspicious and others are not. This problem was explored in a case decided in the Supreme Court of California called *Tarisoff v The Board of Regents of the University of California*[7]. There are similar

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[6] 551 P 2d 334; 17 Cal 3d 425 (1976).

[7] *Ibid.*

problems in the field of the case of AIDS and HIV status. Questions arise in such circumstances where persons, who are patients, refuse to tell a partner or to tell others with whom they are having sexual contact of their HIV status. What circumstances, and with what precautions, would the health professional be authorised to over-ride the will of the patient and give that information to a third party? When should a doctor be authorised by law to breach the wall of confidentiality of medical information to reveal to family members information about a patient's genome which the patient wishes to keep secret?

The third category is *third parties* generally. The issue which has agitated most concern here relates to the provision of information to employers and insurers. I leave aside employers. In terms in insurers, the issue is this: should an insurer be entitled to have completely uncontrolled access to an insured's genetic information? The arguments in favour of dong so are several. We allow insurers to have ordinary, old-fashioned health checks. We allow them to have heart tests and blood tests. Giving them genetic data is merely adding an extra dimension of accuracy. It is unreal to prevent insurers from having that information, so they say. But the argument against agreeing to this is that insurance has hitherto been worked out on a basis of the sharing of risks. If insurers can get this information there may be no risks. Insurers would be finding absolutely predictable certainty. Therefore, in order that we as a community continue to share risks fairly amongst each other, should we reserve the risk and prevent insurers having access to this data which would, in effect, make some people uninsurable? It is a very difficult question to resolve. In some countries, legislation has been enacted to forbid insurers getting access to this information. In others, the provision has been made that insurers cannot seek the information because the concern from the privacy point of view is that the data subject, the insured, or applicant for insurance, is so vulnerable that they may sign away rights and that that will, in effect, allow the insurer to get this information with the insured's "consent", not truly voluntary but enforced.

The fourth category involves *researchers*. The debate in this area took me back to some of the debates we have twenty years ago in the OECD Committee on Privacy. Is it enough to say that researchers should have complete access to anonymised information? Or should we, as some countries have done, insist that even in terms of anonymised information, you have a right, as the data subject, to control that information and to prevent it from going to others? Is that a legitimate privacy interest? Or would we take the view that, once information has been anonymised for statistical purposes, the individual has lost any legitimate control over or interest in it. It cannot harm the individual. Therefore, it should go forward into research in that form?

The final category is *the State*. In terms of international principle, the State has many obligations. But what are the rights of the State? What is the position of the State in terms of a national DNA bank? Would that be the ultimate universal identifier which would be completely uncopyable, which would provide the ultimate peril to individual privacy?

I will never forget a conference which I attended in Paris, early in the days of my work with the OECD Committee on Privacy. It was so long ago that President Giscard D'Estaing was there. At the conference the participants were talking about privacy and universal identifiers. Suddenly I saw a bearded man who looked a little like an anarchist, leap to his feet. He started to hammer the table. It was too fast for my understanding of French. So I picked up the earphones and started to listen. Never forget, he was saying, pointing his finger at the President, that before the War, the Netherlands introduced with typical Dutch efficiency, an identity card which had a metal strip through it. It was impossible or extremely difficult to imitate, to reproduce. In France they had an ordinary old red card with a little photograph on it. This was the reason why 97% of Netherlands Jews perished in the Holocaust - they could not forge false identity papers to allow their escape. But France was able to save most of its Jews. This was because France did not have the card with the little metal strip. Sometimes efficiency is not in the best interests of liberty.

In terms of an identification card, a DNA identifier, a national universal DNA identifier would be completely unbeatable. Even the Netherlands could not surpass it. So these are some of the problems which the UNESCO Committee and the HUGO Committee are working with.

THE UNESCO DECLARATION & THE CHALLENGE AHEAD

In terms of the draft *Universal Declaration*, it is structured in this way. First of all the human genome. It talks in Part A, Article 1 of recognising that the human genome is the common heritage of humanity. That is the sort of general statement one tends to find in international instruments. Then it gets down to more nitty-gritty matters. Part B talks of research on the human genome. Part C deals with the rights of the person concerned. Part D deals with conditions for the exercise of scientific activity in relation to the genome. Part E deals with what it calls the "duty of solidarity". Part F with the promotion of the principles in the *Declaration*. Part G with implementation of the *Declaration*. It is likely that the *Universal Declaration* will go to the General Conference of UNESCO later this year. The international community is awakening to the issues presented by the Human Genome Project and genomic research. I will attach the present draft of the *Declaration* to these remarks. All interested citizens should be aware of it.

So there it is. We have countless bodies which have already ventured on this area. We have international bodies which are venturing on the area. It is a matter of the greatest of importance. Issues of privacy and confidentiality represent just one little aspect of our coming adventures with the genome. At the heart of the Human Genome Project is nothing less than the future of our species. Some people are writing of this topic in terms of the human rights of future generations. It is a matter which, on the cusp of the new millennium, is certainly worthy of the attention of all people who are concerned about the rule of law, human rights and the essential questions of morality. But it is especially important that we engage in the dialogue people of intellect and of the churches to whom other citizens look for guidance and wisdom extending beyond the superficialities of much public debate. It is hard to conceive of a topic that is more important. After all, the future of humanity is a topic that should command a little of our attention.

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UNITED NATIONS EDUCATIONAL,
SCIENTIFIC AND CULTURAL ORGANIZATION

COMMITTEE OF GOVERNMENTAL EXPERTS FOR THE FINALIZATION OF A DRAFT DECLARATION ON THE HUMAN GENOME

(Paris, 22-25 July 1997)

DRAFT OF A UNIVERSAL DECLARATION ON THE HUMAN GENOME AND HUMAN RIGHTS

The General Conference,

Recalling that the Preamble of UNESCO's Constitution refers to "the democratic principles of the dignity, equality and mutual respect of men", rejects all "doctrine of the inequality of men and races", stipulates "that the wide diffusion of culture, and the education of humanity for justice and liberty and peace are indispensable to the dignity of men and constitute a sacred duty which all the nations must fulfil in a spirit of mutual assistance and concern", proclaims that "peace must be founded upon the intellectual and moral solidarity of mankind", and states that the Organization seeks to advance "through the educational and scientific and cultural relations of the peoples of the world, the objectives of international peace and of the common welfare of mankind for which the United Nations Organization was established and which its Charter proclaims",

Solemnly recalling its attachment to the universal principles of human rights, affirmed in particular in the Universal Declaration of Human Rights of 10 December 1948 and in the two International United Nations Covenants on Economic, Social and Cultural Rights and on Civil and Political Rights of 16 December 1966, in the United Nations Convention on the Prevention and Punishment of the Crime of Genocide of 9 December 1948, the International United Nations Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Declaration on the Rights of Mentally Retarded Persons of 20 December 1971, the United Nations Declaration on the Rights of Disabled Persons of 9 December 1975, the United Nations Convention on the Elimination of All Forms of Discrimination

Against Women of 18 December 1979, the United Nations Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power of 29 November 1985, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Standard Rules on the Equalization of Opportunities for Persons with Disabilities of 20 December 1993, the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction of 16 December 1971, the UNESCO Convention against Discrimination in Education of 14 December 1960, the UNESCO Declaration of the Principles of International Cultural Co-operation of 4 November 1966, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the ILO Convention (N° 111) concerning Discrimination in Respect of Employment and Occupation of 25 June 1958 and the ILO Convention (N° 169) concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989,

Bearing in mind, and without prejudice to, the international instruments which could have a bearing on the applications of genetics in the field of intellectual property, *inter alia*, the Bern Convention for the Protection of Literary and Artistic Works of 9 September 1886 and the UNESCO Universal Copyright Convention of 6 September 1952, as last revised in Paris on 24 July 1971, the Paris Convention for the Protection of Industrial Property of 20 March 1883, as last revised at Stockholm on 14 July 1967, the Budapest Treaty of the WIPO on International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures of 28 April 1977, and the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) annexed to the Agreement establishing the World Trade Organization, which entered into force on 1st January 1995,

Bearing in mind also the United Nations Convention on Biological Diversity of 5 June 1992 and *emphasizing* in that connection that the recognition of the biological diversity of humanity, shall not give rise to any interpretation of a social or political nature which could call into question "the inherent dignity and (...) the equal and inalienable rights of all members of the human family", in accordance with the Preamble to the Universal Declaration of Human Rights,

Recalling 22 C/Resolution 13.1, 23 C/Resolution 13.1, 24 C/Resolution 13.1, 25 C/Resolutions 5.2 and 7.3, 27 C/Resolution 5.15 and 28 C/Resolutions 0.12, 2.1 and 2.2, urging UNESCO to promote and develop ethical studies, and the actions arising out of them, on the consequences of scientific and technological progress in the fields of biology and genetics, within the framework of respect for human rights and freedoms,

Recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but *emphasizing* that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics,

Proclaims the principles that follow and *adopts* the present Declaration.

A. HUMAN DIGNITY AND THE HUMAN GENOME

Article 1

The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.

Article 2

a) Everyone has a right to respect for their dignity and for their human rights regardless of their genetic characteristics.

b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 3

The human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment including the individual's state of health, living conditions, nutrition and education.

Article 4

The human genome in its natural state shall not give rise to financial gains.

B. RIGHTS OF THE PERSONS CONCERNED

Article 5

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

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

c) The right of each individual to decide whether to be informed or not on the results of genetic examination and the resulting consequences should be respected.

d) In the case of research, protocols shall, in addition, be submitted for prior review in accordance with relevant national and international research standards or guidelines.

e) If according to the law a person does not have the capacity to consent, research affecting his or her genome may only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law. Research which does not have an expected direct health benefit may only be undertaken by way of exception, with utmost restraint, exposing the person only to a minimal risk and minimal burden and if the research is intended to contribute to the health benefit of other persons in the same age category or with the same genetic condition, subject to the conditions prescribed by law, and provided such research is compatible with the protection of the individual's human rights.

Article 6

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

Article 7

Genetic data associated with an identifiable person and stored or processed for the purposes of research or any other purpose must be held confidential in the conditions foreseen by law.

Article 8

Every individual shall have the right, according to international and national law, to just reparation for damage sustained as a direct and determining result of an intervention affecting his or her genome.

Article 9

In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons within the bounds of public international law and the international law of human rights.

C. RESEARCH ON THE HUMAN GENOME

Article 10

No research or its applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over the respect for human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.

Article 11

Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted. States and competent international organizations are invited to co-operate in identifying such practices and in determining, nationally or internationally, appropriate measures to be taken to ensure that the principles set out in this Declaration are respected.

Article 12

a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard to the dignity and human rights of each individual.

b) Freedom of research, which is necessary to the progress of knowledge, is part of the freedom of thought. The applications of research, including those in biology, genetics and medicine, concerning the human genome, shall seek to offer relief from suffering and improve the health of individuals and humankind as a whole.

D. CONDITIONS FOR THE EXERCISE OF SCIENTIFIC ACTIVITY

Article 13

The responsibilities inherent to the activities of researchers, including meticulousness, caution, intellectual honesty and integrity in carrying out their research as well as in the presentation and utilization of their findings, should be the subject of particular attention in the framework of research on the human genome, because of the ethical and social implications. Public and private science policy-makers also have particular responsibilities in this respect.

Article 14

States should take appropriate measures to foster the intellectual and the material conditions favourable to freedom in the conduct of research on the human genome and to consider the ethical, legal, social and economic implications of such research, on the basis of the principles set out in this Declaration.

Article 15

States should take appropriate steps to provide the framework for the free exercise of research on the human genome with due regard for the principles set out in this Declaration, in order to safeguard respect for human rights, fundamental freedoms and human dignity and to protect public health. They should seek to ensure that research results are not used for non-peaceful purposes.

Article 16

States should recognize the value of promoting, at various levels as appropriate, the establishment of independent, multidisciplinary and pluralist ethics committees to assess the ethical, legal and social issues raised by research on the human genome and its applications.

E. SOLIDARITY AND INTERNATIONAL CO-OPERATION

Article 17

States should respect and promote the practice of solidarity towards individuals, families and population groups who are particularly vulnerable to or affected by disease or disability of a genetic character. They should foster *inter alia* research on identification, prevention and treatment of genetically-based and genetically-influenced diseases, in particular rare as well as endemic diseases which affect large numbers of the world's population.

Article 18

States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.

Article 19

a) In the framework of international co-operation with developing countries, States should seek to encourage that:

- i) the assessment of the risks and benefits pertaining to research on the human genome is ascertained and abuse is prevented;
- ii) the capacity of developing countries to carry out research on human biology and genetics, taking into consideration their specific problems, is developed and strengthened;
- iii) developing countries can benefit from the achievements of scientific and technological research so that their use in favour of economic and social progress can be to the benefit of all;
- iv) the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine is promoted.

b) Relevant international organizations shall support and promote the measures taken by States for the aforementioned purposes.

F. PROMOTION OF THE PRINCIPLES SET OUT IN THE DECLARATION

Article 20

States should take appropriate measures to promote the principles set out in the Declaration, through education and relevant means, including *inter alia* through the conduct of research and training in interdisciplinary fields and through the promotion of education in bioethics, at all levels, in particular addressed to those responsible for science policies.

Article 21

States should take appropriate measures to encourage other forms of research, training and information dissemination conducive to raising the awareness of society and all of its members of their responsibilities regarding the fundamental issues relating to the defence of human dignity which may be raised by research in biology, in genetics and in medicine, and the applications thereof. They should also undertake to facilitate on this subject an open international discussion, ensuring the free expression of various socio-cultural, religious and philosophical opinions.

G. IMPLEMENTATION OF THE DECLARATION

Article 22

States should make every effort to promote the principles set out in this Declaration and should, by means of all appropriate measures, promote their implementation.

Article 23

States should take appropriate measures to promote, through education, training and information dissemination, respect for the aforementioned principles and to foster their recognition and effective application. States should also encourage exchanges and networks between independent ethics committees, as they are established, to foster full collaboration.

Article 24

The International Bioethics Committee of UNESCO should contribute to the dissemination of the principles set out in this Declaration and to further the examination of issues raised by their applications and the evolution of the technologies in question. It should organize appropriate consultations with parties concerned, such as vulnerable groups. It should make recommendations, according to UNESCO's statutory procedures, addressed to the General Conference and give advice concerning the follow-up of this Declaration, in particular the identification of practices that could be contrary to human dignity, such as germ-line interventions

Article 25

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 and fundamental freedoms, including *inter alia* the principles set out in this Declaration