

Freedom of Expression and Enquiry

Introduction

My intention in this paper is to examine the concept of freedom of enquiry, with particular reference to scientific and medical research and to examine the extent to which it is given effect as a legal concept both within international human rights law and in Irish law. I intend to compare it with freedom of expression, to which it is related, a right which has given rise to far more litigation and analysis, and to explore some similarities and differences between the two concepts. The right to impart or receive information is rendered useless if one is not entitled to discover that information in the first place. It could, therefore, be argued that the right to freedom of scientific research or enquiry is an aspect of freedom of expression.¹ I will then go on to consider whether there is adequate protection given to the right to carry out scientific research through constitutional law and international human rights instruments.

I will then discuss the abuses which can arise through the misuse of scientific research particularly in relation to the issue of consent of human subjects. Following this, I refer to areas which have been problematical in relation to scientific research, the protection of the human genome, human cloning and the use of human embryos in stem cell research. Finally, I raise the question whether there is a need for regulation in the area of biomedicine.

I have tried to aim this paper at the listener who may not have a specialist knowledge in legal concepts so I apologize in advance to those to whom the concepts involved will be familiar. As I am a lawyer and not a scientist, insofar as I have to refer to scientific matters I apologize also for my very imperfect grasp of complexities which I think I can appreciate if not always understand.

When Legal Rights Collide

What happens when two legal rights come into collision with one another? It is important to recall that very few rights can be regarded as absolute and not capable of being derogated from. One of the few which does fall into this category is the right not to be subjected to torture, though even with regard to this right one well-known American scholar, Alan Dershowitz, has suggested that torture should be permitted in circumstances where it could be used to obtain information which could save lives.² So far his views have not generally met with favour among lawyers. Nevertheless as noted most rights are not absolute, even the right to life is not unqualified, and legal systems generally permit life to be taken by a person acting in necessary and proportionate self-defence.

Limitations on freedom of expression

Many legal systems give the right to freedom of expression extensive protection and recognize only very precise circumstances in which it can be limited. For example, in the European Convention on Human Rights freedom of expression is given a very high value which can only be restricted for the reasons which are specified in Article 10(2).

Any restrictions on the right must be clearly provided for in law. The reasons which may justify a restriction are, firstly, for national security, territorial integrity or public safety, secondly, for the prevention of disorder or crime, thirdly, for the protection of health or morals, fourthly, for the protection of the reputation or rights of others, fifthly, for preventing the disclosure of information received in confidence, and finally, for maintaining the authority and impartiality of the judiciary.

The restriction in question must be both necessary and proportionate to the aim to be achieved. Necessity is a very strict test: it will only be met if there is no other means to achieve the purpose which is sought.

The European Court of Human Rights has found that freedom of expression constitutes one of the essential foundations of a democratic society, one of the basic conditions for its progress and the development of every person.³ It has consistently held that speech which shocks, offends and disturbs is protected.⁴ The Court has, for example, upheld the right of political parties to campaign for fundamental changes to the legal and constitutional structures of a state, provided that this is done through legal and democratic means, and provided also that the change sought is itself compatible with fundamental democratic principles.⁵ In the United States of America freedom of speech has been afforded a particularly strong position in constitutional law. There, the courts have gone so far as to uphold the burning of the national flag as an act of free speech which is constitutionally protected.⁶

In the Constitution of Ireland, by contrast, the right to freedom of expression is much more qualified.

Article 40.6.1° of the Constitution of Ireland provides as follows:

“The State guarantees liberty for the exercise of the following rights, subject to public order and morality:-

i. The right of the citizens to express freely their convictions and opinions.

The education of public opinion being, however, a matter of such grave import to the common good, the State shall endeavour to ensure that organs of public opinion, such as the radio, the press, the cinema, while preserving their rightful liberty of expression, including criticism of Government policy, shall not be used to undermine public order or morality or the authority of the State.

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The publication or utterance of blasphemous, seditious, or indecent matter is an offence which shall be punishable in accordance with law.”

As a result of the restriction on the freedom of expression in the interests of public order, morality or State security, the constitutional protection of freedom of expression in the Constitution of Ireland is much weaker than that afforded by either the European Convention system or the United States Constitution.

In fact, the Constitution of Ireland not merely *permits* exceptions to the right to freedom of expression, but requires the creation of exceptions in relation to blasphemous, seditious or indecent matter, and requires them to be enforced by criminal sanctions, as was shown recently when the Oireachtas created a new criminal offence of blasphemous libel, in response to this constitutional imperative.⁷

Here it is worth recording that the Constitution Review Group, which reported in 1996, and of which I had the honour to be a member, referred to the protection of free speech in the Constitution of Ireland as “weak and heavily circumscribed” and quoted the observation that:

“A guarantee of freedom of expression may have been enshrined in the ... Constitution of 1937 but its formulation was so qualified and ambivalent as to leave expression and information issues virtually untouched and unlitigated for several decades to come.”⁸

The weakness of the Irish constitutional guarantee may be gauged by the fact that for the first thirty years of the Constitution’s existence Ireland had one of the most severe censorship regimes in any democratic state, yet no challenge based on the constitutional guarantees was brought against that censorship regime, nor is it likely that any such challenge would have succeeded.

The Constitution Review Group recommended major changes to the guarantee of freedom of expression in the Constitution of Ireland. It argued that the right to free expression should not be subject to the test of public order and morality and the authority of the State, since this test is too all-embracing. Instead, it proposed a qualification based on public interest following the model of Article 10 of the European Convention on Human Rights.⁹ It also proposed removing the constitutional offences of the publication or utterance of blasphemous, seditious or indecent matter. Thirteen years on, those recommendations have not been followed. The Irish political system is not geared towards making long-term systemic change where no immediate or urgent problem has been identified.

Reconciling Conflicting Legal Rights

As already noted, under the European Convention system, the exceptions to the rights which are protected are set out in the Articles of the Convention and are strictly construed. Any interference with a right must be necessary, must be provided for by law, and must be only such as is proportionate to the aim to be achieved.

In Irish constitutional law, a slightly different approach to the reconciliation of rights is adopted although the net result is somewhat similar. Here two different techniques may be used. The first is that of harmonious interpretation, under which if possible an attempt will be made to reconcile the rights which may appear to be in collision. This is in accordance with the idea that the Constitution has to be read as a whole and given a harmonious interpretation where possible. But it is not always possible to reconcile two rights and sometimes courts are faced with a stark choice. In such circumstances the Irish courts adopt the idea of a hierarchy of rights, under which preference will be given to the right which is determined to be the superior right. In a number of cases, for

example, the courts have held that the right to a fair trial is a superior right to other rights such as the community's right to prosecute crime and where a conflict between the two cannot be resolved then the right to a fair trial must take precedence.¹⁰ In determining such issues a court will have regard to the degree of interference the exercise of one right will have on another and will take account of the actual circumstances of the case.

Freedom of expression and freedom of research

The right to freedom of expression is in a somewhat different category to other rights because generally speaking the actual act of expression does not in itself directly impinge on other rights, but rather the damage is likely to be caused by the reaction of a third party to the words which are spoken or written. This is perhaps one reason why legal systems tend to be reluctant to permit limitations to the freedom of expression. Of course, there are some circumstances in which the mere act of saying something directly impinges on another right. The utterance of defamatory speech can in itself deprive another person of his or her reputation. Similarly it is frequently pointed out that there can be no right to shout fire in a crowded theatre as to do so is certainly likely at least to cause alarm and panic, and at worst to lead to injury and even death. However in most cases the damage done by words will come about indirectly because of the action which third parties take on foot of them. For example, where a person incites another to commit a crime, that in itself may cause no harm unless some person acts on foot of the incitement. Nevertheless incitement to crime is regarded as sufficiently serious to amount to criminal conduct even where it is not acted upon.

There are obvious similarities and links between the right to freedom of expression and a right to carry out research or seek information.

Freedom to carry out research has often been seen as a part of freedom of thought or expression. For example, the Universal Declaration on the Human Genome and Human Rights, which was adopted in 1997 by the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO), states that "freedom of research, which is necessary for the progress of knowledge is part of freedom of thought".¹¹ Similarly, the explanatory memorandum to the Charter of Fundamental Rights of the European Union describes the right to freedom of the arts and scientific research as being "deduced primarily from the right to freedom of thought and expression."¹² The Belgian Court of Arbitration has described the principle of academic freedom as having a twofold basis in the Belgian Constitution, being the consequence both of freedom of expression and freedom of education.¹³

However, in some respects there are also differences between the freedom to carry out research and the freedom of thought or expression. Unlike freedom of expression, the carrying out of a scientific experiment will often have a direct impact on something or someone else. This is likely to be so particularly when one is dealing with the life sciences. Not surprisingly, most of the more controversial issues in relation to freedom of scientific enquiry and research arise in the fields of medicine, biology and genetics where specific research potentially conflicts with the right to life or with the dignity of human beings.

Constitutional and Human Rights Protection for the Freedom of Scientific Research

Freedom of expression is universally protected in express terms in constitutions, bills of rights and general international human rights instruments. By contrast, this is by no means the case in relation to the freedom to carry out scientific research. There is, for example, no express protection for freedom of research or enquiry or for academic freedom in the Constitution of Ireland. Nor is such a right expressly guaranteed in the European Convention on Human Rights, although arguably it might be derived by implication from the right to freedom of expression in Article 10.

The earliest example of a guarantee of the right to scientific enquiry appears to be that contained in Article 27 of the Universal Declaration of Human Rights of 1948 which provides that:

1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share scientific advancement and its benefits.
2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Note, however, that while the Universal Declaration guarantees the right to share in the benefits of scientific advancement no mention is made of the right to carry out scientific investigation or enquiry. When the United Nations elaborated the principles of the Universal Declaration in two United Nations Covenants, the right to scientific research was placed in the International Covenant on Economic, Social and Cultural Rights rather than the justiciable International Covenant on Civil and Political Rights. Article 15 of the Economic, Social and Cultural Rights Covenant effectively repeats the language of Article 27 of the Universal Declaration and in addition provides (at paragraph 3) that “the States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.” The principal difference between the two Covenants is that the Economic, Social and Cultural Rights Covenant provides a weaker guarantee in that the rights it guarantees are to be achieved progressively whereas the Civil and Political Rights Covenant commits the parties to it to respect the rights it guarantees. Furthermore, where states have adopted the Optional Protocol to the Covenant, any breach of a right under the Covenant can be the subject of a complaint to the Human Rights Committee, which can deliver an opinion against the state concerned.

With regard to constitutional protection for the freedom of scientific research and enquiry, Ireland is not alone in not providing such protection. Most European countries whose constitutions date from before 1948 (and some which are later) similarly have no such provision. These include Belgium, Denmark, France, Germany, the Netherlands, Norway, and Sweden. In the case of Sweden this is so despite the fact that the Swedish constitution (which dates originally from the early nineteenth century) contains very elaborate provisions in relation to freedom of expression and the freedom of the press. However, constitutions adopted more recently do tend to contain a provision

guaranteeing rights to scientific research as well as artistic endeavour. The Italian constitution, adopted in 1948, provides that “the arts and sciences as well as their teaching are free”.¹⁴ Article 20 of the Constitution of Spain adopted in 1978, guarantees the right to literary, artistic, scientific and technical production and creation as well as the right to academic freedom. The same article also protects freedom of expression and communication. Almost all of the constitutions adopted in the emerging democracies of central and eastern Europe after the collapse of communism guaranteed the freedom of artistic creation and scientific research, as well as the right to benefit from the achievement of scientific progress. Many of them also guarantee the autonomy of universities and institutions of higher education.

The Charter of Fundamental Rights of the European Union has followed the tendency of recently drafted national constitutions. Article 13 of the Charter provides as follows:

“The arts and scientific research shall be free of constraint. Academic freedom shall be respected.”

The Lisbon Treaty has incorporated the Charter.¹⁵ It follows that rights under the Charter will now be interpreted and applied by the European Court of Justice in the same way as other Community law rights. However, the Charter is addressed to the Union rather than its Member States.

Abuses of Scientific Research

There have been many occasions in the past when shocking abuses of human rights were carried out in the name of scientific or medical research. The worst examples are well known and include the atrocities carried out by Dr. Mengele and others in the concentration camps in Nazi Germany under the guise of medical experimentation and the “experiments” carried out in the USSR in Stalin’s time by Prof. Ilya Ivanovich with the intention of interbreeding humans and chimpanzees. Such abuses of human rights were by no means confined to totalitarian states, as the infamous example of the “Tuskegee Study of Untreated Syphilis in the Negro Male” demonstrates. This study concerned 616 African American males, who were given blood tests in 1932. Four hundred and twelve of those were diagnosed with syphilis. The test subjects were not told they had syphilis and were not treated for it despite the fact that after 1943 penicillin was available as a cure. The purpose of the research was to study the long term effects of untreated syphilis. The research was discontinued only in 1972 after a journalist reported on it. Meanwhile many medical experts had been aware of the study and had raised no objection.¹⁶ What all these examples of human rights abuses have in common is that they were carried out on the subjects of the experimentation without their consent.

In the wake of the Nazi experiments and the subsequent “doctors’ trial” at Nuremberg attempts were made to formulate ethical principles under which research involving humans might be carried out. The first attempt was in the Nuremberg Code in 1947 which was derived from the judgment in the doctors’ trial¹⁷. It emphasized the requirement for voluntary consent of the human subject of research and the weighing of the expected benefits of research against the risks to participants. The Declaration of

Helsinki of the World Medical Association adopted in 1964 set out ethical principles in relation to human experimentation and is regarded as the ethical cornerstone of biomedical research in human subjects. After the Tuskegee case came to light in 1972 the US Congress created a National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research which published ethical principles generally known as the “Belmont Report” in 1979. Three general principles were identified: respect for persons and particularly those with diminished autonomy, the principle of doing no intentional harm while maximizing benefits and minimizing risks, and the fair distribution within society of risks and benefits (for example, not carrying out research among those who will not benefit).

Consent to Medical Research

The International Covenant on Civil and Political Rights contains an important provision relating to scientific research. That is the provision in Article 7 which prohibits the carrying out of scientific or medical experimentation on human beings without their consent. This again is a provision which is commonly found in recent national constitutions. Article 3 of the Charter of Fundamental Rights of the European Union provides, among other things, that in the field of medicine and biology the free and informed consent of subjects must be obtained.¹⁸

The question of consent to medical experimentation is also dealt with in two international human rights instruments that aim to protect people against the misuse of medical and biological advances: the UNESCO Universal Declaration on Bioethics and Human Rights adopted in 2005 and the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the application of Biology and Medicine adopted in 1997 (the Oviedo Convention).

The UNESCO Declaration provides a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics.¹⁹ It sets out a number of general principles to be observed. Human dignity, human rights and fundamental freedoms are to be fully respected. The interests and welfare of the individual are to have priority over the sole interest of science or society.²⁰ The fundamental provision in relation to consent is that 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. Where persons do not have the capacity to consent, authorization should be obtained in accordance with the best interests of that person.²¹ Research should only be carried out for the direct health benefit of the person who cannot consent and if there is no research alternative of comparable effectiveness with research participants who are able to consent. Research which does not have potential direct health benefits should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden. The Declaration also provides that benefits resulting from scientific research should be shared with society as a whole and with the international community, in particular with developing countries.²²

The Oviedo Convention contains similar principles to the UNESCO Declaration. The Convention is an important instrument on human rights and biomedicine. Many of the Member States of the Council of Europe have ratified the Convention though Ireland is

not yet a party to it. The Convention's starting point is the concept of the dignity and identity of all human beings. The Oviedo Convention contains provisions similar to those in the UNESCO Declaration both in relation to consents and to procedures to be followed where persons are unable to consent.²³ Where the research does not have the potential to provide direct benefit to the research subject's health, it may be authorized where it has the aim of contributing, through significant improvement in the scientific understanding of the individual's disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons with the same disease or disorder, and only where the research entails minimal risk and burden for the individual concerned.²⁴

Speaking on 4 December 2002 in Seanad Éireann the then Minister of State at the Department of Health and Children, Mr. Ivor Callely T.D. explained that Ireland was not a party to the Oviedo Convention "because there are difficulties with a number of articles that have implications for the destruction of human embryos." He did not specify which articles were in question. However, he went on to state as follows:

"I am deeply concerned about the absence of statutory controls in regard to a range of interventions in the sphere of assisted human reproduction, including that of human cloning. While medical practice in the area of reproductive medicine is governed by Medical Council guidelines, these only apply in the case of registered medical practitioners and would be ineffective in the case of any service provided by other persons."²⁵

The Minister went on to describe the Government's establishment of the Commission on Assisted Human Reproduction in 2000 and the need to have an informed debate.²⁶

Now that we have the benefit of detailed work from this Commission as well as the advice of the Irish Council for Bioethics it is important that progress should be made towards implementation of the Oviedo Convention, if necessary with reservations or declarations. In the absence of such implementation many areas of scientific research remain unregulated with the exception of the area of clinical trials. Outside of this area there is, on the one hand, no effective regulation of the unscrupulous researcher who is not subject to medical ethics, while on the other hand there is the problem that the absence of proper regulation leaves the legal situation unclear and exposes the researcher to possible legal action by private bodies of citizens.

Clinical Trials

The area of clinical trials is regulated by the European Community Directives which have been transposed into Irish law.²⁷ The implementing Irish Regulations cover investigations which are undertaken to ascertain the efficacy or safety of medicinal products in human subjects. Non-interventional trials – trials involving licensed medicines that are used within the terms of the licence – are governed by the Control of Clinical Trials Acts 1987 – 1990.²⁸

The Regulations provide for a regime of approval of clinical trials by ethics committees as well as detailed rules requiring consent of subjects who participate in clinical trials. There are conditions and principles for the protection of subjects capable of consenting,

subjects incapable of consenting and subjects that are minors. The Regulations state that clinical trials shall be conducted in accordance with the ethical principles set out in the Declaration of Helsinki and that the rights, safety and the well being of the trial subjects shall prevail over the interests of science and society.²⁹ The Regulations now extend to tissue-engineered products.³⁰

The Human Genome

Genetic science has undergone dramatic changes in recent years. Developments include genetic testing and gene therapy. Genetic testing consists of medical examinations aimed at detecting or ruling out the presence of hereditary illnesses or predisposition to such illnesses by directly or indirectly analyzing the genetic heritage of an individual. It is now possible to identify with much greater precision than ever before those who carry specific genes for major single gene disorders such as cystic fibrosis, hemophilia, Huntington's disease as well as those who carry genes which may increase their risk of developing major disorders later in life such as heart disease, cancer and Alzheimer's disease. It is also possible to identify genes which while they are not responsible for single gene disorders nevertheless contribute to the development of major disorders. In some cases testing may offer the possibility of timely preventive treatment or the opportunity to diminish risks through modification in lifestyle or environment.

However, in other cases knowledge of a genetic problem will not necessarily mean there is a solution to be found. For this reason the right not to know can sometimes be as important as the right to know. This also gives added importance to the right of free consent. A further complicating factor is that genetic testing may have implications not only for the individual but for his or her relatives. For all these reasons it is important to limit the applicability of predictive testing to cases where this can be used for the benefit of the health of the subject of the testing. It is also important to ensure that health testing for the benefit of third parties such as insurance companies as distinct from health testing for the benefit of the subject is prohibited. An insurance company should not be entitled to subject the decision whether to issue an insurance policy to the holding of a predictive genetic test. Nor should an employer be entitled to require a potential employee to undergo such a test. The use of human genetics data for employment purposes is inconsistent with the UNESCO Declaration and the Oviedo Convention.³¹

The Oviedo Convention contains provisions relating to the human genome. Article 11 of the Convention prohibits any form of discrimination on grounds of genetic heritage. The Convention states that any intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and provided its aim is not to introduce any modification in the genome of any descendants.³² Also under the Convention, the use of techniques of medically assisted procreation should not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.³³

In 1997 UNESCO adopted a Universal Declaration on the Human Genome and Human Rights. Its point of departure is the dignity of the human being. The human genome is described as underlying the fundamental unity of all members of the human family, as

well as the recognition of their inherent dignity and diversity. It is described in a symbolic sense as the heritage of humanity.³⁴ The Declaration proclaims everyone's right to respect for their dignity and their rights regardless of their genetic characteristics. Human dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.³⁵ The Declaration includes principles on prior-informed consent, confidentiality of data, reparation, protection of public health, benefit-sharing and international cooperation.

Cloning

Reproductive cloning means the creation of an organism that is a genetic copy of another existing organism. Scientists have successfully cloned a number of animals and these include cats, dogs, cows, horses, deer, pigs, rabbits, sheep, mice and rats. The technique has been described as "highly inefficient" as there is less than a one per cent chance of obtaining a live birth.³⁶ Also unpredicted problems have arisen in all of the mammals cloned so far leading to a high rate of foetal abnormalities and prenatal death and to health problems of those animals born alive.

Article 3 of the Charter of Fundamental Rights of the European Union prohibits the reproductive cloning of human beings. The Charter is, however, addressed to the Union rather than its Member States. The UNESCO Declaration on the Human Genome and Human Rights provides in Article 11 that "practices which are contrary to human dignity such as reproductive cloning of human beings shall not be permitted".

The Council of Europe has adopted an additional protocol to the Oviedo Convention prohibiting the cloning of human beings. The Protocol, adopted in 1998, notes that the cloning of human beings may become a technical possibility, but considers that the instrumentalization of human beings through the deliberate creation of genetically identical human beings is contrary to human dignity and thus constitutes a misuse of biology and medicine and also refers to the serious difficulties of a medical, psychological and social nature that the deliberate cloning of human beings could imply for all the individuals involved. For these reasons, the Convention prohibits any intervention which seeks to create a human being genetically identical to another human being, whether living or dead.³⁷ Adherence to the protocol is open only to parties to the Oviedo Convention.³⁸ Domestic Irish law has yet to prohibit reproductive cloning.

Stem Cell Research and the use of Human Embryos

Undoubtedly the most difficult ethical and legal problems at the moment in the field of scientific research relate to the use of human embryos. At this stage, it will be clear that I am not a scientist or a medical person, and I neither could nor do I intend to attempt to describe all of the amazing developments which have been taking place in this field in recent years. I would, however, recommend anyone who is interested in the area to read the Irish Council for Bioethics Opinion on Ethical, Scientific and Legal Issues concerning Stem Cell Research (2008) which can be found on the Council's website: <http://www.bioethics.ie/uploads/docs/lowStemCellReport.pdf>.

Briefly, the Report explains that stem cells are immature cells from which all specialized cell types can be derived. There are two basic types, adult stem cells and

embryonic stem cells. Adult stem cells are found in various sites in the body such as bone marrow, the brain, blood, the eye, the liver. Generally speaking adult stem cells have a relatively limited capacity to turn into more specialized cells. For example, the adult stem cells found in blood can transform into the various different blood cells but not into, for example, skin cells.

Embryonic stem cells are the cells which are found in the developing embryo at a very early stage of development and have a capacity to develop into any of the different cell types that make up the human body. They begin to specialize as the embryo develops into a foetus. Stem cells can be isolated and used to generate lines of stem cells in the test tube.

Stem cells have potentially huge implications for medicine. Potentially they can be used to replace and repair diseased cells in the human body and are therefore of potential value in all illnesses and disorders characterized by diseased or damaged cells.

The ethical and legal questions relating to stem cells arise in relation to embryonic stem cells. There is no particular ethical objection in principle to the use of adult stem cells. The characteristics of embryonic and adult stem cells differ. Embryonic stem cells are not only more versatile in their potential development but are capable of multiplying much more rapidly than is the case with adult stem cells. On the other hand, the risks attached to rejection in the case of transplanting cells would be less for adult stem cells. A diseased person's own stem cells could be used to create stem cell lines and thereby avoid the risk of rejection.

The technology in this area is advancing very rapidly and there is, for example, a possibility that adult stem cells may have the potential of being "dedifferentiated" – in other words turned into stem cells which are capable of being developed into a greater variety of cell types than is the case with the differentiated adult stem cells produced in the human body. The Irish Council for Bioethics Report points out that there is an emerging consensus among stem cell researchers that a continuum of stem cell types exists, with foetal stem cells, for example, lying somewhere in between embryonic and adult stem cells in terms of their ability to transform into a variety of specialized cell types.³⁹ The Report points out that at present it is very difficult to predict which type of stem cell might be most successful in treating various diseases and conditions and concludes that "many scientific bodies converge on the view that research using all types of stem cells, including human embryonic stem cells, represents the optimal strategy for the advance of stem cell research and the delivery of therapies".⁴⁰

The ethical and legal questions in relation to the use of embryonic stem cells arise, of course, from the question of what moral value we ascribe to an embryo. The embryos which are used in stem cell research are the surplus frozen embryos which arise as a byproduct of assisted human reproduction. If not used in stem cell research they would either be frozen indefinitely or destroyed.

There are those who believe that full moral value should attach to life from the moment when the sperm fertilizes the ovum and that the resulting organism, starting with two cells and dividing into four, eight and so on, has already the moral quality of a human being. Persons who hold this view believe that any act which is carried out and results

in the destruction of the embryo and its ability to progress on the path towards birth is morally unacceptable. On the other hand, others do not ascribe such a moral value to an 8 or 16 cell embryo resulting from *in vitro* fertilisation and consisting entirely of undifferentiated stem cells, and which does not have a nervous system or any ability to perceive anything or feel pain, even though if implanted in the womb it would have the potential to develop into a foetus and eventually be born as a human body.

The legal issue in Ireland, of course, arises because of the constitutional protection given to the “unborn” as a result of the Eighth Amendment to the Constitution made in 1983.

Unfortunately, there is no definition within the Constitution of an “unborn”, nor, despite judicial pronouncements, has the Oireachtas attempted to define it by legislation. Even if it were permissible to examine the question by reference to what was stated at the time of the referendum by proponents of the amendment – a process which is probably not admissible from a legal point of view – one would still find quite a variety of opinion. There is no doubt that many of those who promoted the amendment were strongly of the opinion that life begins at the moment of conception and that what they wished to protect was that life from that very moment. At the same time, there were those who denied that an effect of the constitutional amendment would be to render unlawful such practices as the use of the morning after pill which if they were correct must mean that “unborn” is not referable to pre-implantation embryos.

Be that as it may, the legal position in Ireland remains unclear. In the recent decision of *MR v TR & the Attorney General*,⁴¹ the High Court declined to hold that the word “unborn” in Article 40.3.3 includes embryos outside the womb or *in vitro*. The case concerned a dispute between an estranged husband and wife over the status of three frozen embryos which were created by *in vitro* fertilization. Mr. Justice McGovern stated as follows:

“It is not for the courts to decide whether the word “unborn” should include embryos *in vitro*. This is a matter for the Oireachtas, or for the people, in the event that a Constitutional Amendment is put before them. In 2000 the Government established a Commission on Assisted Human Reproduction to make recommendations in the area of *in vitro* fertilization practices.⁴² ... In March, 2005 the Commission published its report in which it made forty recommendations, most of which were unanimous. ... A majority of the Commission recommended that “the embryo formed by IVF should not attract legal protection until placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*”. It is a matter for the Oireachtas as to whether they implement the recommendations of the Commission. In the meantime the Courts are being asked to deal with a complex dispute involving social issues which should be governed by a regulatory regime established by an Act of the Oireachtas.”

I understand that this case is currently under appeal and the decision of the Supreme Court on the point will be awaited with great interest. The Irish Council on Bioethics in a strongly worded conclusion to its 2008 Report stated as follows:

“It is the view of the Council that, a failure to provide a comprehensive and cohesive regulatory system to govern stem cell research and its applications undermines the moral value of the human embryo. It may also hinder developments in this field of research in Ireland. Thus, the Council recommends the establishment of a State funded regulatory authority, which would function independently and transparently (in its principles and agenda), to oversee embryo research. Such an authority should be tasked with the registration, licensing and inspection of persons/premises/activities working with human embryos and/or embryonic material. Furthermore, the authority should develop codes of good practice for professionals working in the area and provide accessible information for the public.”⁴³

The European Union has established a European Group on Ethics in Science and New Technologies (EGE). The Group’s task is to examine ethical questions arising from science and new technologies and on this basis to issue opinions to the European Commission in connection with the preparation and interpretation of Community legislation or policies. In an opinion published in November 1998 entitled “Ethical Aspects of Research involving the use of Human Embryos in the context of the 5th Framework Programme”, the EGE stated that the human embryo deserved legal protection and that such protection fell under the remit of national legislation. The EGE recognized the difficulty in standardizing such legislation throughout individual Member States and acknowledged that it would be inappropriate for the EU to impose one exclusive moral code. In Ireland public funding has been restricted to adult stem cell research. The Irish Government has adopted the position that European funding for embryonic stem cell research will not be permitted in Ireland but it has not sought to prevent the EU providing funding for research in those countries where it is permitted.⁴⁴

Conclusion

The Constitution of Ireland provides for the right to freedom of expression of convictions and opinions, but the qualifications the Constitution permits have the result that the constitutional protection of freedom of expression is relatively weak compared to, for example, the European Convention on Human Rights. The proposals of the Constitutional Review Group in 1996 to strengthen the constitutional guarantees in this area have not been acted upon.

The right to scientific research is not referred to in the Constitution of Ireland but is recognized in the EU Charter of Fundamental Rights. Clinical trials are regulated by legislation and medical doctors are bound by a code of ethics, but in the important area of biomedicine there is otherwise an absence in Ireland of regulation. Ireland is not yet a party to the Oviedo Convention or its protocols in this area. Furthermore, despite the constitutional protection given to the unborn there has been no legislation to give it effect or define its scope. Consequently questions remain concerning the legality of various avenues of scientific research and the absence of legal regulation is likely to act, on the one hand, as an inhibition toward the genuine researcher without, on the other hand, imposing a clear prohibition on techniques such as reproductive cloning which it is generally agreed ought to be prohibited.

¹ Curiously the case law of the European Convention on Human Rights appears to be silent on the point.

² *Why Terrorism Works, Understanding the Threat, Responding to the Challenge* Yale University Press, 2002

³ *Handyside v. U.K.* (Application 5493/72) (1976) 1 EHRR 737

⁴ *Ibid*

⁵ *Refah Partisi (The Welfare Party) and Others v. Turkey* (Applications Nos 41340/98, 41342/98, 41343/98, 41344/98 Judgment of 13 February 2003)

⁶ *Texas v. Johnson* 491 US 397 (1989)

⁷ Section 36 of the Defamation Act 2009

⁸ McGonagle, "Freedom of Expression and Information" Irish Human Rights Yearbook 1995 at p. 130 (quoted at 291 in the Report of the Constitution Review Group)

⁹ Report of the Constitution Review Group 1996 at p. 301

¹⁰ In the case of *D v. DPP* [1994] 2 IR 465 Denham J. stated:

"The applicant's right to a fair trial is one of the most fundamental constitutional rights afforded to persons. On a hierarchy of constitutional rights it is a superior right. A court must give some consideration to the community's right to have this alleged crime prosecuted in the usual way. However, on the hierarchy of constitutional rights there is no doubt that the applicant's right to fair procedures is superior to the community's right to prosecute."

¹¹ Article 12(b)

¹² Explanation to Article 13 (see www.europarl.europa.eu/charter/convent49_en.htm)

¹³ Quoted in the published constitutional decisions collected by the Venice Commission's Codices BEL-2005-3-016 at www.codices.coe.int/NXT/gateway.d11/CODICES/precis/eng/eur/bel/bel-2005

¹⁴ Article 33(1)

¹⁵ Article 6(1) of the Treaty of Lisbon states:

"The Union recognizes the rights, freedoms and principles set out in the Charter of Fundamental Rights of the European Union of 7 December 2000, as adapted at Strasbourg, on 12 December 2007, which shall have the same legal value as the Treaties."

¹⁶ For a brief outline of the case and a bibliography see www.onlineethics.org

¹⁷ Annas, G. and Grodin, M., *The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation*, 1992, Oxford University Press

¹⁸ Article 3 reads as follows:

"Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
 - the free and informed consent of the person concerned, according to procedures laid down by law;
 - the prohibition of eugenic practices, in particular those aiming at the selection of persons;
 - the prohibition on making the human body and its parts as such a source of financial gain;
 - the prohibition of the reproductive cloning of human beings."

¹⁹ Article 2

²⁰ Article 3. Article 4 of the Declaration provides that "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 provides that the autonomy of persons to make decisions is to be respected and persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

²¹ Article 7

²² Article 15

²³ Article 16

²⁴ Article 17

²⁵ 170 Seanad Debates Col. 1528

²⁶ <http://www.dohc.ie/publications/cahr.html>

²⁷ EC (Clinical Trials on Medicinal Products for Human Use) Regulations 2004 – 2009 which transposed the European Communities Clinical Trials Directive 2001/20/EC into Irish law. The 2004 Regulations have been amended by EC (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2004; the EC (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations 2006; and the EC (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulations 2009.

²⁸ Section 2(4) of the Control of Clinical Trials Act 1987 as inserted by section 22 of the Irish Medicines Board (Miscellaneous Provisions) Act 2006 states that:

“(4) The provisions of this Act shall not apply in respect of any clinical trial that is subject to control under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations 2004”

²⁹ Part 2 of Schedule 1 of the Regulations as inserted by the EC (Clinical Trials on Medicinal Products for Human Use) (Amendment No. 2) Regulations 2006

³⁰ The EC Regulations initially applied only to medicinal products which were defined as:

“(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.” (Article 1(1) of Directive 2004/27/EC)

Since the amending regulation, EC (Clinical Trials on Medicinal Products for Human Use) (Amendment) Regulation 2009, the Regulations apply to “tissue engineered products” in the same manner as the Regulations apply to medicinal products for gene therapy and somatic cell therapy. A “tissue engineered product” means a product that:

“— contains or consists of engineered cells or tissues, and

— is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue.

A tissue engineered product may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances, such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices.

Products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action, shall be excluded from this definition.”

(Article 1(b) of Regulation (EC) No 1394/2007)

³¹ See UNESCO Declaration, Articles 9, 10 and 11. See also Article 5 of the UNESCO Declaration on Human Genetic Data (16 October 2003). Article 12 of the Oviedo Convention provides that predictive genetic tests may be used only for health purposes or scientific research.

³² Article 13

³³ Article 14

³⁴ Article 1

³⁵ Article 2

³⁶ The Report of the Irish Council on Bioethics at p.20

³⁷ Article 1

³⁸ Article 4

³⁹ The Report of the Irish Council on Bioethics at p.15

⁴⁰ *Ibid* p. 16

⁴¹ Unreported, High Court, 15th November 2006

⁴² The judgment referred to the fact that “The members of the Commission included a wide range of experts in the fields of reproductive medicine embryology genetics law and other relevant areas which can be ascertained from the description of the members of the Commission published at the commencement of their report. The Commission also invited a number of additional experts with complementary expertise in specific areas including Philosophers, Sociologists, a Director of Ecumenical Studies and a Roman Catholic Theologian.”

⁴³ The Report of the Irish Council on Bioethics at p. 67

⁴⁴ The position of the Irish Government in relation to this matter is discussed at pages 66 and 67 of the Irish Council on Bioethics Report.