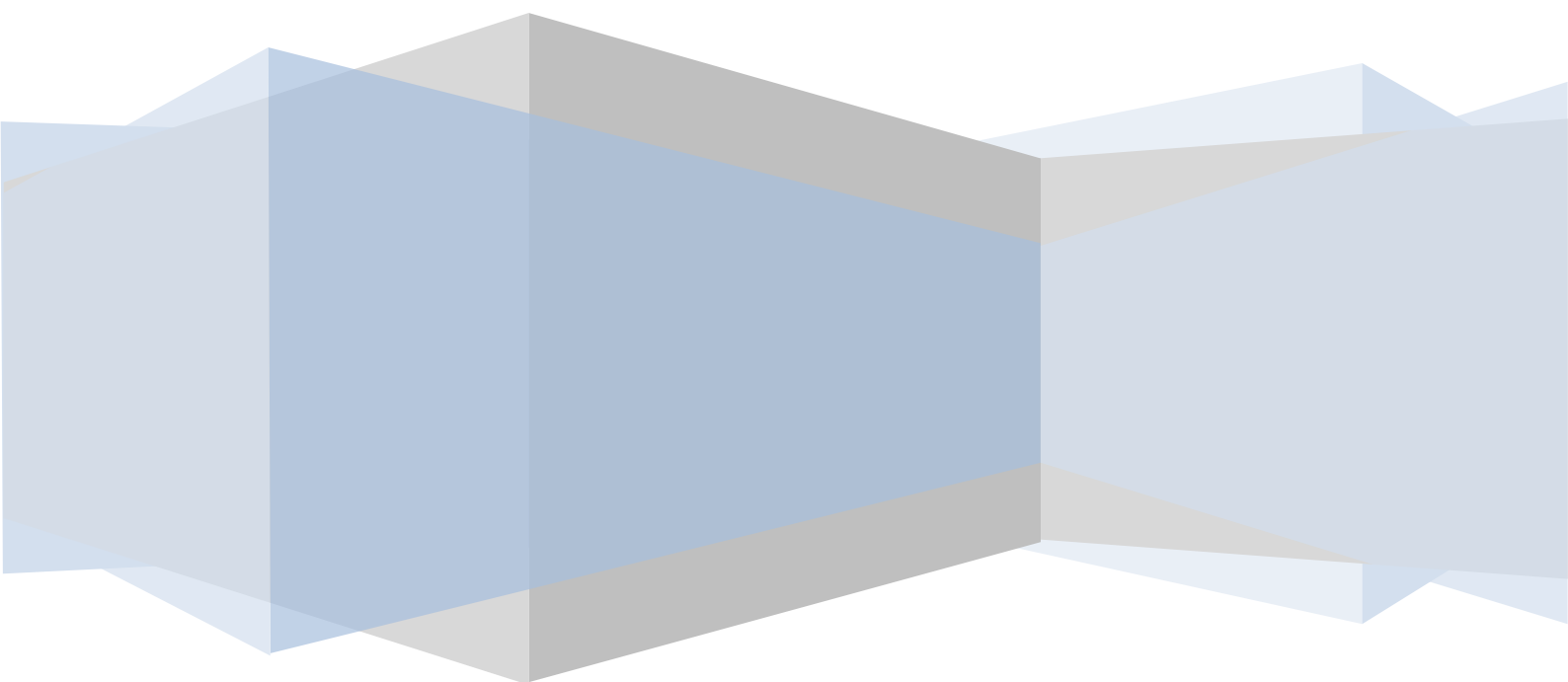


# Irish public policy and human embryonic stem cell research

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## **Public Policy and Human Embryonic Stem Cell Research Dr Fionnuala Gough (on behalf of the Irish Stem Cell Foundation)**

### **Introduction**

Public policy generally takes the form of legislation, court rulings or the active prohibition of an activity by a government or agency charged with the funding and regulation of that activity. In a pluralistic society there will always be some people who benefit from and some who are burdened by policy decisions. The goal of policy makers should be to pursue policies that promote human health and society's best interests while 'striving to be the least offensive to the most persons.' (Holland et al., 2001;199)

Human embryonic stem cell research currently presents unprecedented public policy and regulatory challenges, with the therapies derived from hESCR having the potential to deeply affect lives but it has become an area of bioethical and public policy controversy across the world.

In Ireland it has long been apparent that 'unborn life is something which represents a most important social value', particularly since the insertion of the 8<sup>th</sup> amendment to the Constitution, Article 40.3.3, in 1983 (Cox, 2008;103). However, Irish political leaders have failed to respond to the question of whether or not human embryonic and stem cell research should be permitted to take place within Ireland. There is currently no Irish legislative framework regulating either research involving human embryos and human embryonic stem cells or assisted human reproduction (AHR) despite the fact that assisted reproductive technologies have been available since 1987 (Madden, 2002;126, Mills, 2007;300).

### **Policy Positions and hESCR**

Throughout the Western world a range of regulatory regimes exist which aim to protect the interests of the *in vitro* embryo, patients and society as a whole. They have been identified by Knoepffler as falling into one of four possible positions: A, B, C and D (Knoepffler, 2004; 55-74) (Walters, 2004;3-38)( Jones and Towns, 2006; 1113-1116) .

**Position A** prohibits all human embryo research, including the utilisation of human embryonic stem cells, while those countries which fall into **Position B** allow research to proceed on hES cells extracted before a specific dead-line but no research is permitted on embryos (Jones and Towns, 2006; 1113).

**Position C** permits research on and the isolation of hESCs only from embryos which are surplus to requirement of clinical IVF programmes, governed by the 14-day embryo research limit, (HFEA 1990; s.13), while **Position D** additionally allow research on embryos produced specifically for research by somatic cell nuclear transfer (SNCT) into human ova (Madden, 2008; 386)( Mills, 2007;454)( Jones and Towns, 2006;1114).<sup>i, ii</sup>

Within the European Union (EU) there has been a diverse response to the legal and ethical questions posed by human embryo and embryonic stem cell research and their potential benefits, which reflect in part the philosophical, economic and social differences between the member states. The traditional presumption underlying the liberal democracies that are part of the EU, is that individuals have the right to determine and choose their own ends through their autonomous informed choices. Therefore, the greater the perceived benefit of a procedure to an individual, the stronger must be the public interest justification for constraining it (Johnston and Petersen, 2008;716-728).

Government regulation, or lack of it, can encourage or inhibit research(Winston, 2007; 27-34). EU member states which have responded with liberal, permissive regulatory regimes to research involving embryos include Belgium, Sweden and the UK.

The UK was one of the first countries in the world to introduce legislation regulating embryo research through the *Human Fertilisation and Embryology Act 1990*. The main aim of this Act was to establish a Human Fertilisation and Embryology Authority (HFEA) which oversees all aspects of ART in the UK, and provides the government with information and advice (Mason and Laurie, 2006; 71-119). This Act has undergone several revisions since 1990, with the effect that the UK applies policy **Position D** to hESC research. The UK has subsequently become the most productive country in Europe in terms of publications in the area of hESC research and significant investments have been directed to hESC research within the UK (Winston,

2007; 27-34). In contrast, Germany drafted a more restrictive regime, the *Stem Cell Act 2002* which banned all research involving hESCs from German patients and attached ‘the most important of all constitutional values, human dignity, to the foetus’(Cox, 2008; 91).<sup>iii</sup> Despite this, German scientists, with ethical approval, could import human embryonic stem cells lines which had been produced in the UK, as long as they were created before January 1<sup>st</sup> 2002, when the restrictive law came into effect (Heinemann and Honnefelder, 2002; 530-543). This is effectively Position **B**. (Walters, 2004; 3-38)

German scientists subsequently complained, however, that this placed them at a disadvantage compared to their peers in other countries and had campaigned for a re-consideration of the 2002 law. This campaign was successful in April of 2008 when a revision of the law was passed by the Lower House of the German Parliament which allows the extension of the cut-off date of May 1 2007 for the importation of stem cell lines, thereby increasing the number of cell lines available to German Scientists from 40 to 500. This revision was welcomed by the German Minister for Science, the President of the Max Planck Institute, and the Federation of German Industries as being ‘key to fostering research in Germany’ and keeping ‘German researchers competitive internationally’.<sup>iv</sup> With regard to other EU States, the Czech Republic, Denmark, Finland, Greece, Hungary and the Netherlands have adopted Position C, either explicitly or *de facto*, while Poland, Austria and Italy have effectively adopted **Position A** (Walters, 2004; 3-38)( Jones and Towns, 2006;1113-1116).

Unsurprisingly, the European Commission in its report on hESC research found that there is no consensus across the EU about what the limits and conditions for research should be, nor what protections are afforded to the human embryo (Halliday, 2004;41, Harris et al., 2005;158). However, no jurisdiction, no matter how permissive its regime, has produced legislation denying human embryos some moral status.

### **hESC Research Policy in Ireland**

Despite the lack of legislation to date in Ireland, there have been attempts to develop policy in this area. In March 2000 the Irish Government established the Commission on Assisted Human Reproduction (CAHR) to report ‘on the possible approaches to the regulation of all aspects of assisted human reproduction and the social, ethical and

legal factors to be taken into account in determining public policy in the area'. The Commission acknowledged that the achievement of *in vitro* fertilisation presented:

'the medical profession and through them society as a whole with the dilemma created by the existence of embryos which will not be used for their intended purpose.'

One of the purposes of the Commission was to force Irish society:

'to face the question whether, for the first time in the history of mankind, human embryos may be used for purposes other than human reproduction' ( Report of CAHR, 2007; v foreword) <sup>v</sup>

The Commission published its report in 2005 containing 40 recommendations. The main recommendations addressed the regulatory issues with the first of these been that 'a regulatory body should be established by an Act of the Oireachtas to regulate AHR services in Ireland'. <sup>vi</sup>

This recommendation follows international best practice. The regulatory body would be independent and would have the function of advising the government on all matters relating to AHR and associated procedures including research. There would be provision within the legislation for regular review in order to accommodate medical, scientific and social development. <sup>vii</sup>

As part of its report, the Commission undertook a public consultative process with regard to opinions regarding AHR through canvassing, public advertisement, public conference, and telephone interviewing of a representative sample of the population. A questionnaire was designed to measure public attitude towards AHR and embryo research. In its executive summary the report notes that evidence from these indicates that public opinion 'ranges from total opposition to all forms of AHR on the one hand to uncritical acceptance of any assistance that science can give to infertile people on the other'. <sup>viii</sup>

The Commission considered the arguments for and against embryo research recognising the existence of three basic positions:

(i) research should not be permitted; (ii) research should be permitted but only on surplus embryos; and (iii) research should be permitted on surplus embryos and on embryos specifically generated for research. <sup>ix</sup>

With one exception, all members of CAHR were in favour in principle of the second position. A majority of CAHR members also recommended that embryo research, including embryonic stem cell research should be permitted on surplus embryos that are donated for research, for specific purposes only and under stringently controlled conditions up to 14 days following fertilisation. The conditions and purposes for which embryo research is permitted would be stipulated by the regulatory body.<sup>x</sup>

Most importantly, a majority of the Commission recommended that

‘the embryo formed by IVF should not attract the legal protection until it is placed in the human body, at which stage it should attract the same level of protection as the embryo formed *in vivo*.’<sup>xi</sup>

The CAHR strongly advised that the creation of IVF embryos for research should be prohibited and further recommended that both reproductive cloning and the generation and use of interspecies or hybrid embryos should be prohibited.<sup>xii</sup>

To date, none of the recommendations of the CAHR have been enacted in legislation by the current government.

In April 2008 the Irish Council on Bioethics (ICB) published ‘An Opinion on the ethical, scientific and legal issues in stem cell research’. This report provides a comprehensive overview of the background to the current scientific and legislative debate about the generation and use of embryos and stem cells in research, and of the ethical issues central to these debates.<sup>xiii</sup> It notes that there is currently no legal impediment to the importation or use of stem cell lines into Ireland by scientists as they, unlike doctors working in the same field, are not bound by the guidelines from the Irish Medical Council. In their ‘Guide to Professional Conduct and Ethics for Registered Medical Practitioners’ the Irish Medical Council currently provides the only recommendations pertaining to this area of research in Ireland. (7<sup>th</sup> Edition, 2009). The guidelines, to which any practicing medical doctor must adhere or risk censure or even being removed from the register of medical practitioners, had stated in relation to IVF in an earlier edition (2004) that ‘any fertilised ovum must be used for normal implantation and must not be deliberately destroyed’(IMC Guidelines, 2004;36). The guide also stated that, ‘the creation of new life forms for experimental purposes or the deliberate and intentional destruction of *in vitro* human life already formed is professional misconduct’(IMC Guidelines, 2004; 35)<sup>xiv</sup>

This has been revised in the new edition to simply state that a doctor:

‘should not participate in creating new life forms solely for experimental purposes’ and should not ‘engage in human reproductive cloning’ (Irish Medical Council, 2009; 21).

It would appear, therefore, that researchers who are not registered medical practitioners have no legal constraints on their carrying out embryonic and stem cell research. However, the ICB does note that:

‘notwithstanding the lack of specific legislation pertaining to stem cell research in Ireland, within Europe there are a number of overarching regulatory frameworks in existence, which have implications for the legislative and regulatory processes for stem cell research that are adopted in Ireland. The European Convention on Human Rights and Biomedicine (1997) makes a number of references to research involving embryos and cloning. Article 18.1 of the Convention permits research on embryos *in vitro* where National legislation allows, provided the embryos are afforded sufficient protection’. (Opinion of ICB, 2008;64)<sup>xv</sup>.

Ireland, however, has not yet ratified this convention.

Overall the Report of the Bioethics Council acknowledges that:

‘societal attitudes in relation to these questions vary greatly, with some people fundamentally opposed to research involving nascent human life, while others take the view that research on human embryos offer a legitimate opportunity to garner new scientific and medical knowledge’. (Opinion of ICB, 2008; Foreword, *ii*)<sup>xvi xvii</sup>

In the past policy-makers have fallen back on a claim of general societal anxiety as a rationale for their lack of legislative action. Despite a lack of political will, given the significance of the issues involved, such reservations should not be allowed to hinder policy development. It would seem a more logical response to these concerns to construct an effective and comprehensive regulatory structure, as according to Johnston, regulatory systems that:

‘acknowledge and respond to public fears and doubts provide a sense of control, offer public access and influence and offer a forum and time for discussion and education in that space between knowledge and ignorance that trust must occupy’ (Johnston and Petersen, 2008; 716-728) .

In the conclusion to its review of regulatory frameworks, the ICB stated that the failure by Ireland to provide just such a comprehensive and cohesive 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’ (Opinion ICB, 2008; 67).<sup>xviii</sup>

In the current regulatory lacuna with no legal impediment to the importation of stem cell lines by scientists, some academic institutions involved in research have attempted to forge their own pathway. In November 2008 the governing body of University College Cork (UCC) recommended by a slim majority (16 to 15) that the University’s Academic Council should allow hESC research at UCC ‘under strict guidelines drawn up by the University Research Ethics Board (UREB)’. (Gartland, 2008, Culliton, 2008b)

A statement from UCC confirmed that it had taken cognisance of the two expert independent reports published in this context in recent years – the CAHR Report (2005) and the Irish Bioethics Council Opinion (2008) in drawing up its guidelines. It reiterated that ‘in the absence of either national legislation or policy, the university has sought to take steps that would ensure that the strictest internal control over research in this area.’ (Culliton, 2008b)

The guidelines permit the importation of hESC lines once the scientific merit of the proposed research has been established. The feasibility of using alternative research methods that do not require hESCs will be scrutinised before permission to use hESC lines is given, while approval of all research projects must be by majority of UREB members after consideration of the scientific and ethical issues.

The proposal of UCC’s governing body does not recommend destructive research on living human embryos.

UCC was compelled to draw up and approve these proposals because of the total absence of national legislative measures to guide future research within the university. They were able to do so as it remains unclear as to whether or not embryo and embryonic stem cell research actually violate any existing constitutional provisions. Trinity College Dublin has followed UCC in introducing similar guidelines recently.

In response to UCC's proposals Senator Rónán Mullen, an independent senator representing NUIG, proposed the introduction of a 'Stem-Cell Research (Protection of Human Embryos) Bill into Seanad Éireann in November 2008<sup>xix</sup>. In the explanatory memorandum to the Bill it states that it aims:

'to regulate stem cell research in the State by prohibiting embryo-destructive research and related activities, such as the creation of human embryos, human clones or human-animal hybrids for research purposes'.<sup>xx</sup>

During the course of the debate in the Seanad, Minister of State at the Department of Enterprise, Deputy Devins, speaking on behalf of the Government, acknowledged that there currently is no legislation in Ireland 'governing intervention in the natural process of creating human life'.

This Bill, if enacted, would also prohibit the use of any cell lines derived from embryos, even if the research from which the cell lines were obtained took place outside the jurisdiction. Several senators spoke against the absolutist nature of this bill while emphasising that they agreed with Senator Mullen that there is a great need to legislate in this area. The problem with this particular proposal, however, was that it did not hold out any prospect of regulation; rather it simply banned hESC research altogether. They also felt that the Bill in this form sent out a message that Ireland was not open to scientific research.<sup>xxi</sup> No vote on this Bill was taken in the Seanad despite vigorous debate.

Policy development in the past in Ireland in the area of human reproduction has sometimes relied on the judiciary pushing the executive to act, as happened following *Attorney General v. X* [1992] 1 IR 1, when the decision of the Supreme Court to allow a 14 year old who was pregnant as the result of a rape to travel to the UK for a termination, was followed by a referendum and insertion into the Constitution of the 13<sup>th</sup> and 14<sup>th</sup> Amendments, and by legislation regulating the provision of information about abortion services outside the State, the *Regulation of Information (Services Outside the State for Termination of Pregnancies) Act 1995*.

The consequences of the legislature's failure to address the constitutional ambiguities which have given rise to the uncertain legal position of AHR and human embryonic and stem cell (hESC) research was again held up for public scrutiny when the

judgment in the ‘Frozen Embryos’ case was handed down by the Supreme Court in December 2009.<sup>xxii</sup>

Within their judgments several of the Judges expressed their misgivings as to the role of the Courts in pronouncing ‘on questions as to when human life begins’, and on the absence of a regulatory framework within the State.

Justice Geoghegan expressed his concern about this lack of regulation in the AHR area, whilst acknowledging that ‘the moral and ethical problems in this area are legion’. He continued:

‘there is no common agreement on their resolution. Since most of these problems are of an ultra modern nature, I rather doubt that there is a constitutional solution to them, but this does not mean that there cannot and indeed should not be regulation by the Oireachtas’.

Justice Hardiman was at pains to emphasise that although this case brought up a number of difficult questions, that it was not in the remit of the court to decide when human life begins but rather it should be the legislature that makes such decisions, and the degree of respect that should be afforded to fertilised embryos through its laws. He described the ‘marked reluctance on the part of the legislature actually to legislate on these issues’, and warned that if the:

‘legislature does not address such issues, Ireland may become by default an unregulated environment for practices which may prove controversial or, at least to give rise to a need for regulation’.

Chief Justice Murray agreed that ‘it is for legislatures in the exercise of their dispositive powers to resolve such issues on the basis of policy choices’.

Justice Fennelly also expressed concern at the lack of legislation in this area stating that:

‘it is disturbing, to use no stronger word, that some four years after publication of the Report of the Commission on Assisted Human Reproduction, no legislative proposal has even been formulated’.

The unanimous view of the judges that the courts should not be called upon to state when life begins could be regarded as an abdication of their judicial responsibilities if a judge’s role is regarded as one of interpretation of constitutional provisions.

However, the Supreme Court through its judgment, is effectively criticizing the abdication of legislative responsibility by successive Irish governments in the area of AHR and research involving embryos.

By ruling as they have, the Supreme Court has been forced to decide what is permissible and what is not. In most democratic societies this is what politicians are elected to do.

### **A way forward?**

It is clear that Ireland will in the near future have to face up to the difficult challenge of defining at which point the constitutional protection of the unborn specified by Article 40.3.3 begins, and that finding appropriate policy will involve serious moral debate, and a willingness to be open to compromising policy solutions. The current 'Irish solution' to an 'Irish problem' as applied to hESC research is no solution at all. The lack of a regulatory regime creates confusion and could potentially allow improper research to take place. There are many aspects to the challenges to responsible regulation in this area, including the complexity of the actual science involved, the fact that policy making in this context will engage strongly held moral values, and not least the polarising effect of the abortion debate in Ireland in the past. As evidenced by the ongoing debate about legalising abortion it can be difficult to conduct a debate on an issue of public policy where opposing sides are separated by an apparently unbridgeable chasm of moral disagreement.

The legal position of the embryo under Irish law will almost certainly never rest upon an achieved consensus as to the moral status of the embryo but it is possible to acknowledge this while at the same time showing respect for all parties to the debate. Whatever regulatory scheme is adopted it should reflect the reality that for hESC research and many AHR procedures there is not, and may never be, social consensus regarding the potential 'harms' and potential therapeutic 'benefits' (Caulfield et al., 2004; 414-471).

Dr. Dolores Dooley, chair person of the Irish Council for Bioethics, in response to the current legal uncertainty that exists in Ireland in relation to the appropriate use of non-implanted embryos or the importation of stem cell lines by scientists, called on behalf of the Council for the Oireachtas to establish an independent regulatory authority, which could be tasked with clarifying ambiguities in the meaning of the term 'unborn', and legislating for the registration, licensing and inspection of persons and premises working with human embryos. One of the key arguments she puts forward in

support of such a call was the need to bring to an end the ‘legal vacuum’ that currently exists in this area in Ireland as it not only: ‘undermines the moral value of the human embryo but undermines people working in the field of infertility treatment, and the thousands of couples availing of IVF.’ (Dooley; 2008) (ICB Annual Report 2007-2008; foreword 2-3 )

Any policy initiative in this area which tries to weigh the moral value of human embryos against the moral value of human welfare, is trying to balance an acceptance of the value of human life against the obligation to care for existing human kind generally. The Irish Stem Cell Foundation (ISCF) argues that embryonic research is acceptable in certain contexts and under certain strictly controlled conditions. Defining what those contexts or conditions might be and subsequently securing agreement for them from both the conservative and scientific communities in Ireland is likely to prove difficult.

Both the Report of the Commission on Assisted Human Reproduction and the Opinion of the Irish Bioethics Council have recommended that hESCR be allowed on donated ‘spare’ embryos from IVF cycles up to a maximum of 14 days and that the generation of embryos for research should not be allowed nor should cloning be permitted. The ISCF feels that their approach was measured, and, in considering a wide range of interest groups within Irish society, allowed voice to the concerns of many over this type of research.

The ISCF would therefore support the carefully regulated use of supernumerary IVF embryos – embryos that are otherwise destined to be destroyed - for the purposes of embryonic stem cell research aimed at alleviating human suffering.

If Ireland continues to avoid addressing the difficult ethical issues thrown up by advances in reproductive technology we may find that Ireland is in danger of becoming, the ‘unregulated environment for practices that may be controversial’ of which Justice Hardiman warned, and that we are no longer capable of recognising and appreciating, as Jonsen says, ‘what is normal about being human’ (Jonsen, 1998; 282-321).

What is needed is a greater openness and transparency in stem cell policy and this would be best achieved through the establishment of a regulatory regime which sets

out the limits, as well as the opportunities, for hESC research in Ireland (Caulfield et al., 2004; 414-471).

It is essential, therefore, that Ireland develops a flexible regulatory scheme that respects the ethical and moral values of 21<sup>st</sup> century Ireland while allowing the public / professional dialogue in this area to continue.

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## Notes

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<sup>i</sup> The Human Fertilisation and Embryology ( Research Purposes) Regulations (2001), UK.

<sup>ii</sup> A somatic cell is any cell in the body except for germs cells (sperm and egg cell). In somatic cell nuclear transfer the nucleus of a somatic cell is taken from an organism and transplanted into an egg that has had its own nucleus removed (an enucleated egg). The modified egg is then activated by an electric current or chemicals to stimulate embryonic development.

<sup>iii</sup> Deutscher Bundestag.(2002). Entwurf eines Gesetzes zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen ( *Stammzellgesetz – StZG*) Berlin. Bundestagsdrucksache 14/8394.

<sup>iv</sup> <http://www.dw-world.de/dw/article/0,2144,3259556,00html> Accessed 16/04/2008.

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- <sup>v</sup> Report of the Commission on Assisted Human Reproduction (2005) p. v (foreword). Dublin, Government Publications Office, Molesworth Street. Also available at <http://www.dohc.ie/publications/cahr.html>.
- <sup>vi</sup> Report of the Commission on Assisted Human Reproduction (2005) p.8. Dublin, Government of Publications Office .
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- <sup>viii</sup> Executive Summary. Report of the Commission on Assisted Human Reproduction (2005). p. xii Dublin, Government Publications Office.
- <sup>ix</sup> Executive Summary. Report of the Commission on Assisted Human Reproduction (2005) pxiii
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- <sup>xii</sup> Report of the Commission on Assisted Human Reproduction. (2005) p. 60
- <sup>xiii</sup> ‘Ethical, Scientific and Legal Issues concerning Stem Cell Research’. Irish Council for Bioethics (Comhairle Bitheitice Ná hÉireann) Opinion 2008
- <sup>xiv</sup> A Guide to Ethical Conduct and Behaviour. (2004) Medical Council of Ireland. March.. Section F – Genetic Testing and Reproductive Medicine. 24.1
- <sup>xv</sup> Opinion of Irish Bioethics Council.2008 p64
- <sup>xvi</sup> Opinion of Irish Bioethics Council, 2008 p.11
- <sup>xvii</sup> Report of the Commission on Assisted Human Reproduction, 2005 . p.29
- <sup>xviii</sup> Opinion of Irish Bioethics Council, 2008 p.67
- <sup>xix</sup> Rónán Mullen worked from 1996 to 2001 in the Communications Office of the Archdiocese of Dublin. [www.ronan.mullen.ie/](http://www.ronan.mullen.ie/)
- <sup>xx</sup> An Bille um Thaighde Gaschille (Suthanna Daonna a Chosaint) 2008 Stem-Cell Research (Protection of Human Embryos) Bill 2008. [ No. 60 of 2008] The Stationary Office, Government Publications Sale Office, Molesworth Street, Dublin 2
- <sup>xxi</sup> Senator Ivana Bacik. [www.oireachtas.ie/Seanad](http://www.oireachtas.ie/Seanad) debates 26 November 2008
- <sup>xxii</sup> *Roche v Roche & Ors* [2009] IESC 82