

# The UK Model: Setting the Standard for Embryonic Stem Cell Research?

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## **Introduction**

In the early 1980s the United Kingdom took a pioneering role in the area of new reproductive technologies (NRTs). Significant strides were made not only in terms of scientific and clinical development, but also in relation to relevant legal and ethical issues. In the latter category, attempts were made to address the debate concerning the moral status of human embryos by advocating a “14-day limit” for research: the *Warnock Report*, published in 1985, stipulated that research with human embryos only be allowed up to 14 days after fertilization, the point at which the three germ layers typically become distinct.<sup>1</sup> To many, the proposed moral dividing line was purely arbitrary, yet somehow a quasi-break in the ontogeny of a human being came to be used as a legitimate demarcation point.<sup>2</sup>

In 1990, the U.K. entrenched the 14-day limit in the *Human Fertilisation and Embryology Act*,<sup>3</sup> and since then most other industrialized nations that permit embryo research have followed suit. Draft legislation in Canada,<sup>4</sup> an opinion report issued by France’s Comité Consultatif National d’Ethique (CCNE),<sup>5</sup> the Netherlands’ *Embryos Bill*,<sup>6</sup> and Australia’s National Health and Medical Research Council (NHMRC)<sup>7</sup> all expressly endorse the U.K. position. The United States’ National Institutes of Health (NIH) has identified the formation of the mesoderm as the appropriate limit for embryo research, and notably this coincides with the 14-day limit<sup>8</sup>

At present it is interesting to speculate about whether the U.K. will set the standard for embryonic stem cell research. In January of this year, after lengthy debates, the U.K. Parliament passed the *Human Fertilisation and Embryology (Research Purposes) Regulations 2001*,<sup>9</sup> permitting embryonic stem cell research using either *in vitro* fertilization (IVF) or somatic cell nuclear transfer (SCNT) technology, and thereby condoning therapeutic cloning. For the time being, this position is unique to the U.K. As policy-makers around the world scramble to take a stance on this hotly debated issue, the question is: will the U.K. lead the

way once again? Or, in the alternative, is the U.K. framework regulating embryonic stem cell research flawed, leaving other nation-states to formulate a different set of standards?

## **A. Reacting to the Science: A Comparative Analysis**

In this article, the likelihood that the U.K. position will become the international position is assessed by way of comparison, examining guidelines and reports issued by governments and quasi-governmental bodies in Canada,<sup>10</sup> the United States,<sup>11</sup> the United Nations,<sup>12</sup> Europe,<sup>13</sup> France,<sup>14</sup> the Netherlands,<sup>15</sup> Germany,<sup>16</sup> and Australia.<sup>17</sup> The comparison, illustrative rather than comprehensive, focuses on key aspects of the U.K. scheme, namely: (1) the nature of the research; (2) the origin of the embryonic stem cells; (3) issues surrounding consent; (4) safeguards against commercialization; (5) directed donation; (6) animal/human hybrids and chimeras; (7) oversight mechanisms and the scope of the regulatory framework. It will examine these aspects in relation to policies developed by other jurisdictions. Points of agreement as well as inconsistencies will be highlighted, the goal being to critically evaluate the U.K.’s initiative as a likely or potential international consensus position.

### **(1) Nature of the Research**

Stem cells can be derived from a variety of sources, including adult tissues, umbilical cords, aborted fetuses, and embryos. The present discussion focuses on stem cells of embryonic origin (“ES cells”). ES cells are derived from the isolated inner cell mass of early embryos, cultured to the blastocyst stage.<sup>18</sup>

The Human Fertilisation & Embryology Authority (HFEA), created under s. 5(1) of the *HFE Act*, is the licensing body for research involving embryos (according to s. 9(1) of the *HFE Act*). Assuming a particular research project satisfies

one of the five purposes relating to reproduction described in Schedule 2, s. 3(2) of the Act or one of the three purposes relating to therapeutic applications outlined in the new *Regulations*, the HFEA will grant a license for embryo research. Indeed, the new *Regulations* ensure that research involving both the derivation and use of ES cells is licensable in the U.K.

In contrast, the distinction between derivation and use is all-important in the U.S., in light of the extant Congressional ban on research with embryos which effectively precludes the derivation of ES cells. The NIH obtained a legal opinion in January 1999, taking the view that “by definition, ES cells are not embryos ... thus, ES cell research is not subject to the ... ban.”<sup>19</sup> On this basis, the NIH moved to authorize the research use of ES cells but not their derivation, thereby avoiding, strictly speaking, a violation of the ban.<sup>20</sup>

Under the Bush administration however, federal funding of all ES cell research within U.S. borders was put on hold. Then, on August 9, 2001, the President announced that only research with ES cell lines derived previously – that is, initiated prior to 9:00 p.m. E.D.T. on that date – would be eligible for federal funding. In his address, Bush asserted that roughly 60 viable ES cell lines currently exist in the world. The claim fell under immediate scrutiny,<sup>21</sup> but the NIH has subsequently released a list comprising 64 lines that were purportedly derived in accordance with the criteria outlined by the President.<sup>22</sup> Namely, ES cells “must have been derived from an embryo that was created for reproductive purposes and was no longer needed ... informed consent must have been obtained for the donation of the embryo and that donation must not have involved financial inducements.”<sup>23</sup> In the realm of public funding then, the U.S. now seems to be the most conservative amongst the states that condone ES cell research.

Formerly, when Bush had not yet made his policy decision, Germany enjoyed this position. Under Germany’s *Embryo Protection Law*, which confers full human status from the moment of fertilization, it is illegal to conduct research that is not in the best interest of the embryo. The “generation of human stem cells is permitted ... from fetal tissues only.”<sup>24</sup> Nevertheless, this law supposedly does not preclude research with ES cells derived elsewhere,<sup>25</sup> creating an interest in the importation of these materials.<sup>26</sup> Insofar as German researchers can continue to use new sources of ES cells, while federally-funded American scientists can only

use those created prior to the August 9 deadline, Germany is more permissive.

## (2) Origin of ES Cells

ES cells can be derived from a number of sources: supernumerary embryos remaining from infertility treatment clinics; embryos created by *in vitro* fertilization (IVF) for research purposes (“research embryos”); and embryos created by somatic cell nuclear transfer (SCNT) for research (“SCNT embryos”).

In very general terms, the research use of spare embryos, destined for destruction, is treated as less morally problematic than the creation of research embryos by either IVF or SCNT. Annas, Caplan and Elias, for instance, argue that there is a “moral difference” behind the discarded-created distinction:

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Although the destruction of a human embryo is lamentable, there is a considerable moral difference between creating and destroying embryos solely to obtain stem cells and destroying unwanted human embryos that will never be used for reproductive purposes, to achieve benefit for those with serious diseases and disorders.<sup>27</sup>

On this reasoning, most jurisdictions that allow ES cell research limit the research to discarded infertility treatment embryos.<sup>28</sup>

The U.K. scheme, however, goes further. More precisely, the U.K. legislation does not impose licensing restrictions in relation to the intention with which the embryo was created. Accordingly, research proposing to use embryos expressly created for research purposes, whether by IVF or SCNT (*i.e.* “therapeutic cloning”), falls within the ambit of licensable research. In sharp contrast, other jurisdictions including Canada,<sup>29</sup> prohibit the creation of embryos for ES cell research.<sup>30</sup> For example, the *Embryos Bill* in the Netherlands *prima facie* precludes the use of research embryos: “[t]he performance of scientific research with embryos created specifically for this purpose is prohibited.”<sup>31</sup> Yet the Bill adds a caveat: “[a]dults ... can provide their gametes for the special production of embryos for ... the culturing of embryonic cells intended for transplantations in humans where this can only be achieved using specially created embryos.”<sup>32</sup>

Similar “nuances” (*i.e.* conditional constraints) can be found in the European Group on Ethics (EGE) and United Nations Educational, Scientific and Cultural Organization (UNESCO) documents. The EGE report states that deriving ES cells from research embryos is “ethically unacceptable” so long as “spare embryos represent a ready alternative source,” while the creation of SCNT embryos “would be premature” at present.<sup>33</sup> UNESCO’s statement largely focused upon therapeutic cloning, presenting arguments for and against. Notwithstanding the fact that the organization eventually took the latter position, it clearly emphasized the ongoing consideration of therapeutic cloning.<sup>34</sup> In France, although the CCNE has been openly divided, a majority of the members are in favour of giving therapeutic cloning the go-ahead.<sup>35</sup> Likewise, Australian states may follow suit if the Australian Academy of Science’s (AAS) recommendation to allow research with SCNT embryos gains support.<sup>36</sup> Thus, the global perspective regarding the use of research embryos, particularly SCNT embryos, seems open to change.

### **(3) (Informed) Consent**

A *sine qua non* of ethical research is the informed consent of the research subject. Research participants must be “respected as ends in themselves ... [and given] a fair opportunity to make an informed choice”.<sup>37</sup>

In the U.K., the *HFE Act* clearly requires the consent of the gamete providers,<sup>38</sup> and the consent obtained must specify one or more of several purposes, including the “use for the purposes of any project of research.”<sup>39</sup> The gamete providers must also “be provided with such relevant information as is proper.”<sup>40</sup> What constitutes “relevant information” and when that information should be disclosed is not addressed, nor is the precise timing of the consent request specified. To date, a bill addressing these shortcomings has not been introduced in the U.K. Parliament.

How do other jurisdictions that allow ES cell research compare? A cursory review of the relevant documents reveals important differences with respect to *whose* consent is in fact required, *when* it should be sought, and precisely *what* information must be disclosed. A key problem area concerns the distinction between the gamete providers and embryo providers. They are not necessarily one and the same, especially in the context of infertility treatment clinics, from which supernumerary embryos are obtained.

A report by the U.K.’s Nuffield Council on Bioethics, a precursor document to the *HFE Act* amendments, singles out both “couples undergoing fertility treatment” that have created embryos using their own gametes, and “embryo providers” without appreciating the possible disjunction between the two.<sup>41</sup> Also, France’s CCNE posits that research is contingent upon “the agreement of the procreating couple.”<sup>42</sup> In Europe, the EGE also fails to unequivocally relate whether the consent of the individual(s) undergoing fertility treatment is sufficient.<sup>43</sup>

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In other documents the “who” is relatively clear, but curiously, there is no unanimity between the documents as to whether embryo or gamete providers should provide consent. For example in Canada, two reports preceding the draft

legislation, like the *HFE Act*, required the gamete providers’ consent.<sup>44</sup> In contrast, the NIH and UNESCO stipulate that the embryo providers must give effective consent.<sup>45</sup>

Where the consent of both gamete and embryo providers is mandatory, a discrepancy may arise: a gamete provider consents to the use of his or her gametes for one purpose (*e.g.* reproduction), then subsequently when embryos created with those gametes remain, the embryo provider(s) consents to the use of the embryos for another purpose (*e.g.* research). Canada’s 2001 draft legislation leaves open this loophole: providers of “reproductive material” must consent to the use of their reproductive material “for the purpose of creating an embryo or facilitating human reproduction,” and the embryo “donor[s]” must consent to the use of spare embryos in research,<sup>46</sup> but gamete providers do not have to be informed that embryos containing their genetic material might be used in future research. As the use of donor gametes becomes more common, the likelihood increases that there will be a discrepancy between a person’s original intention in providing gametes for reproductive purposes and the eventual use of these gametes.<sup>47</sup>

The precise nature of the research – stem cell research (and the destruction of embryos) – is undoubtedly “relevant information,” within the meaning of s. 3(1)(b), Schedule 3 of the *HFE Act*, that should always be disclosed. However, the requisite specificity is lacking under the U.K. scheme and others. Some reports simply suggest that the “purpose of the research” must be disclosed while others state that providers should be “as informed as possible.”<sup>48</sup> In the U.S., the NIH report specifically incorporates the nature of the research as a necessary element of disclosure.<sup>49</sup> The

Canadian draft legislation in its Preamble recognizes the need “to promote the principle of free and informed consent as a fundamental condition of the use of human reproductive technologies,” but fails to specify what fulfilling this “fundamental condition” entails.<sup>50</sup>

In addition to answering who should consent and of what they should be informed, a third issue remains: when the providers should be approached for consent. The issue of the timing of consent is only addressed explicitly in one document reviewed, the NIH guidelines. They mandate that consent should be obtained “only at the time of deciding the disposition of embryos in excess of the clinical need.”<sup>51</sup> This proposition, in a fashion analogous to a prior U.S. Commission report, is logically flawed: it assumes that *only* persons who would consent to discarding excess embryos would consent to their use in research.<sup>52</sup> In light of the “pressured context” in which egg donation takes place, Cohen argues that informed consent is needed “not only when [women] dispose of excess embryos, but also when they undergo ovarian stimulation and egg retrieval.”<sup>53</sup> Alternatively, there could be disclosure at the outset of the need for subsequent decision-making concerning the potential fate of supernumerary embryos.<sup>54</sup>

#### **(4) Commercialization**

Comprehensive (and uniform) standards relating to informed consent are critical, in part, because of the commercial interests involved. Lucrative patents are being sought,<sup>55</sup> and licensing agreements and memoranda of understanding are being negotiated, yet the range of financial incentives that the various pieces of legislation and guidelines have sought to address has been limited.<sup>56</sup>

Section 12(e) of the *HFE Act* provides that “no money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorized by directions.” Thus gain, commercial or otherwise, is *prima facie* prohibited, but a means to recoup expenses or circumvent this ban may be achieved through properly enacted directions.<sup>57</sup> Other frameworks that identify commercial concerns have adopted this approach: trade in human gametes is prohibited<sup>58</sup> (except in the U.S., where it is legal to sell gametes), and payment for embryos is prohibited;<sup>59</sup> however, “reasonable cost” expenses incurred by researchers and/or intermediaries are typically reimbursable.<sup>60</sup> The proposed legislation in Canada is unique: it permits gamete providers to recover some expenses.<sup>61</sup>

Indeed, some reports stipulate that the absence of financial benefit is a requisite element of the informed consent given by provider(s),<sup>62</sup> raising the question: why are providers

expected to donate their reproductive material without financial compensation?<sup>63</sup> The typical answer to this question is ‘altruism’. It seems inconsistent, however, to ascribe altruistic motives to would-be gamete and/or embryo providers, “while permitting [if not encouraging] corporations and scientists to profit financially from cells derived by destroying those embryos.”<sup>64</sup> Why not assume that both parties are altruistic or that both are equally interested in financial gain?

Proposed safeguards against commercialization are also undermined by the practice of importing and exporting these reproductive materials. Such practices can occur in the U.K. and Canada pursuant to legislative authority,<sup>65</sup> and elsewhere on a *de facto* basis. As mentioned above, researchers in Germany utilize ES cells derived outside the country’s borders in order to avoid violating embryo protection laws.<sup>66</sup>

The U.K. legislation does not address patenting concerns. Given the *HFE Act*’s date of inception, this is perhaps not surprising; nevertheless, more recent reports worldwide have been silent on the issue as well. Only two of the documents compared give cursory mention to the issue of the patentability of ES cell lines. The U.K.’s Nuffield Council on Bioethics opined that patenting was permissible subject to some limits,<sup>67</sup> while the EGE stated that their views would be announced sometime in the future.<sup>68</sup>

Admittedly, stem cell technology presents a new challenge. Modern property law has not adequately evolved; frozen embryos and ES cells are *sui generis*.<sup>69</sup> In the face of the growing research imperative, however, ES cell guidelines must face commercial issues head-on and at length rather than in a forthcoming document or preamble.<sup>70</sup> In this context, an ad hoc approach is not sufficient: “it makes sense to deliberate before the patents are issued.”<sup>71</sup> Moreover, since “patents are critical for the commercialization process ... we ought to explore ways of harnessing the powerful economic incentives attached to patents as a means of mitigating the ethical concerns associated with the use of patented genetic inventions.”<sup>72</sup> Perhaps, as Caulfield and colleagues suggest, regulatory schemes could require patent holders to guarantee that licensees meet fully informed consent.<sup>73</sup>

#### **(5) Directed Donation**

Some additional parameters are germane to the present comparison against the U.K. baseline. The first of these is directed donation, which refers to the notion that the provider(s) of certain material like an embryo, stipulates to whom the donated material is to be given for therapeutic

purposes. Schedule 3 of the *HFE Act* provides that an embryo may be used for the treatment of the person giving consent or “that person *and* another specified person.” Thus, the wording as well as the context in which the statute was drafted strongly suggest that the other person would be specified where the purpose is reproductive rather than research. In the ES cell context, the various national recommendations differ with respect to directed donation. In the United States, the NIH rejects directed donation and incorporates it as an element to be disclosed to the provider(s) when consent is sought.<sup>74</sup> The EGE, less forcefully, also does not favour directed donation.<sup>75</sup> The remaining reports that affirm the permissibility of ES cell research (Canada’s draft legislation, UNESCO, CCNE, the Netherlands’ *Embryos Bill*, NHMRC, AAS) fail to address this issue.

## **(6) Animal/Human Hybrids and Chimeras**

The *HFE Act* does not definitively preclude the creation of hybrids or chimeras, but both the Nuffield Council and the Donaldson Report preceding the legislative changes, acknowledge that legislative action to that effect is necessary.<sup>76</sup> Internationally, these practices are generally prohibited,<sup>77</sup> though the UNESCO, EGE, and CCNE reports do not address the issue. The proposed Canadian Act, in a manner analogous to the existing *HFE Act* provisions, designates the creation of chimeras and the combination of human and animal genomes as controlled rather than prohibited activities.<sup>78</sup>

## **(7) Oversight and Breadth**

Effective ethics oversight and review is critical in this arena. Although prior to the amendments to the *HFE Act* there was some suggestion that the HFEA’s role in regulating ES cell research was unclear,<sup>79</sup> the *Regulations* did not alter its mandate, and the HFEA’s oversight powers have been preserved. In the U.S., the NIH asserted that the Department of Health and Human Services should establish a stem cell oversight entity.<sup>80</sup> On August 9, 2001, President Bush promised to name a president’s council, comprised of “leading scientists, doctors, ethicists, lawyers, theologians and others ... chaired by Dr. Leon Kass, a leading biomedical ethicist from the University of Chicago,”<sup>81</sup> leaving many details in the U.S. oversight scheme to be worked out. Similarly, in Canada, the draft legislation provides for the creation of an arm’s-length regulatory body that “would be responsible for overseeing the implementation of the proposed legislation.”<sup>82</sup> As in the

U.S., a layer of uncertainty exists; there is no guarantee that the proposal for a regulatory body will survive the rigours of the legislative process. Other general calls for oversight have been issued by France’s CCNE,<sup>83</sup> the Netherlands’ *Embryos Bill*,<sup>84</sup> the UNESCO,<sup>85</sup> the EGE,<sup>86</sup> and the DFG.<sup>87</sup>

## **B. The Regulatory Imperative: Responding to the U.K.’s Lead**

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The U.K.’s position is by far the most “progressive” vis-à-vis the scope of scientific and therapeutic inquiry with ES cells. In contrast to every other state surveyed, the U.K. has sought to license endeavours with research embryos, whether created by IVF or SCNT. While the position is unique to the U.K. for the time being, increasingly, reports are opting to keep therapeutic cloning under close consideration, adhering to an “at this time” approach<sup>88</sup> so often found in judicial dicta. This suggests that other jurisdictions may soon follow suit, and condone therapeutic cloning.

Though this aspect, perhaps the most telling of this story, has yet to unfold, a host of other issues remain unsettled. For instance, the *HFE Act* stipulates that the gamete providers must consent to the research project, whereas other documents place the onus upon the embryo providers or fail to appreciate the relationship between the two. Little if anything could be more critical than the identity of the donor, but the distinction is less a point of disagreement than a misunderstanding. Jurisdictions that require the consent of embryo providers or are imprecise do not diverge, at least not intentionally, from the U.K.’s requirements.

Other consent parameters, including the information to be disclosed, the timing of consent, and whether directed donation can occur, are not adequately addressed by the U.K. regime. It is entirely foreseeable that other policy-makers will also fail to act with respect to these concerns. In terms of the economic forces at play, the *HFE Act* precludes, *prima facie*, gamete providers from financial compensation, while allowing researchers and intermediaries to recover expenses. Internationally, this is the norm, but policy-makers remain insensitive as to their assumptions regarding who should benefit from ES cell research. Though the “innocent researcher” argument as espoused by the California Supreme Court in *Moore v.*

*Regents of the University of California*,<sup>89</sup> is not present in its full form, it is clear that researcher interests have been given priority. In a similar vein, the discussion of patenting issues has been almost non-existent; presumably, jurisdictions do not want to create disincentives for likely investors.

The issue of animal/human hybrids and chimeras, which could arguably be created under the authority of a license pursuant to the *HFE Act*, is one where all states, save for the Canada in its draft legislation, are at odds with the U.K. However, this anomaly only highlights the contextual differences between the *HFE Act* in its original form and more recent efforts to regulate the emerging sphere of ES cell research, where the emphasis has shifted from NRTs to genetic technologies, from reproduction to therapeutic application.

Ultimately then, the U.K. framework is setting the standard. The amendments to the *HFE Act* have given U.K. researchers a great deal of incentive to push the science, a science still in its infancy, in an area of research that is extremely controversial. Some suggest the science is, in a sense, limitless and therefore “the moral imperative of compassion ... compels stem cell research.”<sup>90</sup> The number of diseases that may be cured and the suffering that may be alleviated stipulates that “respect for the embryo must give way to the research imperative.”<sup>91</sup> The public interest in ES cell research and the potential benefits are indeed awesome. At the same time, certain limits insufficiently addressed by the U.K. as well as the rest of the world, particularly those relating to informed consent and commercial interests, need to be put in place. Today and tomorrow there is one true imperative that must take hold, and to which the ES cell research agenda must cede – the regulatory imperative.

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1. M. Warnock, *A Question of Life: The Warnock Report on Human Fertilisation and Embryology* (Oxford: Basil Blackwell, 1985).
2. See F. Baylis, *The Ethics of Ex Utero Research on Spare ‘IVF’ Human Embryos* (Ph.D. Thesis, University of Western Ontario 1989) [unpublished]; see also G. McGee & A.L. Caplan, “What’s in the Dish?” (1999) 29:2 *Hastings Center Report* 36, for a related critique of the developmental approach to embryo status.

3. *Human Fertilisation and Embryology Act* (U.K.), 1990, c. 37 [hereinafter *HFE Act*].
4. Health Canada, *Proposals for Legislation Governing Assisted Human Reproduction* (2001) [hereinafter *Proposals for Legislation*], s. 3(1)(c): “maintain[ing] an embryo outside the body of a woman after the fourteenth day of its development following fertilization or creation, excluding any time in which its development has been suspended [is prohibited].”
5. Comité Consultatif National d’Ethique (CCNE), *Opinion on the preliminary draft revision of the laws on bioethics* (Opinion No. 67, 18 January 2001), online: CCNE <<http://www.ccne-ethique.org>> (date accessed: 29 November 2001). In Part I under the section entitled “The nature of the embryo,” the CCNE notes that the preliminary draft refers to a “stage of development, that of tissue differentiation” as a suitable limit for in vitro development of embryos intended for stem cell research “but suggests the adoption of clearer references in biological terms.” To that end, the *Opinion* recommends that “a reference designating the end of the pre-implantation stage ... i.e. the moment when the embryo acquires the capacity to implant in the uterus” is preferable. Consequently, the CCNE advocates amending Articles L.1245-2 and L.1245-3, sub-paragraph 1 by substituting the phrase “the end of the pre-implantation stage” in place of “the tissue differentiation phase” which is currently included (see Part II). Interestingly, Henri Caillavet, whose approval was conditional on his reservations being appended to the opinion, made the following remark: “[i]t would be preferable to revert to the wording which prohibits embryo development beyond the tissue differentiation stage of the embryo in vitro (14 days) since as we know the United Kingdom accepts a time span which is slightly longer than 14 days.”
6. Netherlands, Ministry of Health, Welfare and Sport, *Bill containing rules relating to the use of gametes and embryos (Embryos Bill)* (26 September 2000), online: Ministry of Health, Welfare and Sport <<http://www.minvws.nl/infotheek.html?folder=4&page=13442>> (date accessed: 30 November 2001) [hereinafter *Embryos Bill*], art. 24(c): “Allowing an embryo to develop outside the human body for longer than fourteen days [is prohibited].”
7. Australia’s National Health and Medical Research Council (NHMRC) recently issued the *National Statement on Ethical Conduct in Research Involving Humans* (1999) containing the following statement: “Research involving assisted reproductive technology is governed by specific legislation in Victoria, South Australia and Western Australia. In other States and Territories those undertaking such research should consult the *NHMRC Ethical Guidelines on Assisted*

- Reproductive Technology (1996).*” Accordingly, this comparison examined the 1996 document, online: NHMRC <<http://www.nhmrc.gov.au/publications/synopses/e28syn.htm>> (date accessed: 30 November 2001) [hereinafter *NHMRC Guidelines*]. Guideline 11.2 reads: “Culturing of an embryo in vitro for more than 14 days [is prohibited].”
8. National Institutes of Health (NIH), *National Institutes of Health Guidelines for Research Using Pluripotent Stem Cells* (Bethesda, MD: NIH, 2000), online: NIH <<http://www.nih.gov/news/stemcell/stemcellguidelines.htm>> (date accessed: 30 November 2001) [hereinafter *NIH Guidelines*], s. I., Scope of Guidelines: stem cells can only be derived from embryos that “have not reached the stage at which the mesoderm is formed.”
  9. S.I. 2001/188 [hereinafter *Regulations*].
  10. *Proposals for Legislation, supra* note 4.
  11. *NIH Guidelines, supra* note 8.
  12. United Nations Educational, Scientific and Cultural Organization (UNESCO), International Bioethics Committee, *The Use of Embryonic Stem Cells in Therapeutic Research: Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research* (BIO-7/00/GT-1/2, Rev. 3, 2001), online: UNESCO <<http://www.unesco.org/ethics>> (date accessed: 30 November 2001).
  13. European Group on Ethics in Science and New Technologies (EGE), *Ethical Aspects of Human Stem Cell Research and Use* (Opinion No. 15, 14 November 2000), online: EGE <[http://europa.eu.int/comm/european\\_group\\_ethics/docs/avis15\\_en.pdf](http://europa.eu.int/comm/european_group_ethics/docs/avis15_en.pdf)> (date accessed: 30 November 2001).
  14. CCNE, *supra* note 5.
  15. *Embryos Bill, supra* note 6; see also Netherlands, Ministry of Health, Welfare and Sport, *Embryos Bill – Brochure: conditions and limitations governing the use of oocytes, spermatozoa, and embryos* (2000), online: Ministry of Health, Welfare and Sport <<http://www.minvws.nl/infotheek.html?folder=4&page=13443>> (date accessed: 30 November 2001) [hereinafter *Embryos Bill Brochure*].
  16. Deutsche Forschungsgemeinschaft (DFG), *Statement of the DFG concerning questions of human embryonic stem cells* (1999), online: DFG <[http://www.dfg.de/english/press/eszell\\_e.html](http://www.dfg.de/english/press/eszell_e.html)> (date accessed: 30 November 2001) [hereinafter *DFG Statement*]; DFG, *New DFG Recommendations concerning Research with human stem cells* (No. 16, 2001), online: DFG <[http://www.dfg.de/english/press/releases/Archive/presse\\_2001\\_16\\_eng.html](http://www.dfg.de/english/press/releases/Archive/presse_2001_16_eng.html)> (date accessed: 30 November 2001) [hereinafter *DFG Recommendations*].
  17. *NHMRC Guidelines, supra* note 7; Australian Academy of Science (AAS), *Therapeutic Cloning for Tissue Repair* (Report from a Forum held on 16 September 1999), online: AAS <<http://www.science.org.au/academy/media/clone2.pdf>> (date accessed 30 November 2001), was also included as part of the Australian picture.
  18. J.A. Thomson *et al.*, “Embryonic Stem Cell Lines Derived from Human Blastocysts” (1998) 282:5391 *Science* 1145.
  19. E. Parens, “Embryonic Stem Cells and the Bigger Reprogenetic Picture” (2000) 10:3 *Women’s Health Issues* 116 at 117.
  20. *NIH Guidelines, supra* note 8 at s. I., Scope of Guidelines: “NIH funds may not be used to derive human pluripotent stem cells from human embryos”; and at s. II.A.2: “[s]tudies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment.”
  21. See *e.g.*, S.G. Stolberg, “U.S. Acts Quickly to Put Stem-Cell Policy in Effect” *The New York Times* (11 August 2001) online: *New York Times* <<http://www.nytimes.com>> (date accessed: 14 August 2001).
  22. National Institutes of Health, *National Institutes of Health (NIH) Update on Existing Human Embryonic Stem Cells* (August 27, 2001), online: NIH <<http://www.nih.gov/news/stemcell/082701list.htm>> (date accessed: 30 November 2001).
  23. *Ibid.*
  24. *DFG Statement, supra* note 16, s. III.
  25. See *e.g.* G. Vogel, “Stem Cell Scorecard” (2000) 290:5497 *Science* 1673; see also *DFG Recommendations, supra* note 16, which acknowledge the practice of importing stem cell lines.
  26. Similarly, researchers in the Australian state of Victoria, where the destruction of embryos is illegal, are obtaining stem cells from Singapore; see *e.g.* J.A. Robertson, “Human embryonic stem cell research: ethical and legal issues” (2001) 2 *Nature Reviews Genetics* 74 at 74.
  27. G.J. Annas, A. Caplan & S. Elias, “Stem cell politics, ethics and medical progress” (1999) 5:12 *Nature Medicine* 1339 at 1340.
  28. *Proposals for Legislation, supra* note 4, s. 8(2). *NIH Guidelines, supra* note 8, s. II.A.2: “[s]tudies utilizing pluripotent stem cells derived from human embryos may be conducted using NIH funds only if the cells were derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the

individuals seeking such treatment.” UNESCO, *supra* note 12 at paragraph 44(b): “[i]f IVF is allowed, as it is in many countries, then it is ethically permissible to use these supernumerary embryos for research and for therapeutic purposes, the only other option being their destruction.” In EGE, *supra* note 13 at 11, s. 1.13, the Group recognizes that “[i]n some countries, draft legislation is being prepared to allow research on stem cells derived from supernumerary embryos after *in vitro* fertilisation.” CCNE, *supra* note 5 in Part I under the section entitled “From medically assisted reproduction to research on the embryos”: “the Committee is in favour of opening up limited and regulated research possibilities on spare embryos.” *Embryos Bill*, *supra* note 6, art. 8(1)(b). The *NHMRC Guidelines*, *supra* note 7, stipulate that developing embryos for purposes other than ART should be prohibited (guideline 11.1) and that “non-therapeutic research which involves the destruction of the embryo...should only be approved...in exceptional circumstances” (guideline 6.4). It follows that spare embryos are the only embryos that can be used in research endeavours under the *NHMRC Guidelines*.

29. *Proposals for Legislation*, *supra* note 4, s. 3(1)(d).
30. *NIH Guidelines*, *supra* note 8, s. III.C: “[r]esearch utilizing human pluripotent stem cells that were derived from human embryos created for research purposes, rather than for infertility treatment [is ineligible for NIH funding].” CCNE, *supra* note 5: “[the] 1994 Act ... specified unambiguously that the creation of human embryos and their destruction for research purposes was prohibited.” Also, art. L.2141-12, sub-para. 1, *ibid.*, states that “[i]n vitro conception of human embryos for research purposes is prohibited” and “conceiving human embryos by *in vitro* fertilisation for research purposes is prohibited.” *Embryos Bill*, *supra* note 6, art. 11: “[t]he performance of scientific research with embryos created specifically for this purpose is prohibited.” *NHMRC Guidelines*, *supra* note 7, guideline 11.1. With respect to therapeutic cloning, see *NIH Guidelines*, *supra* note 8, s. III.D: “[r]esearch in which human pluripotent stem cells are derived using somatic cell nuclear transfer [is ineligible for NIH funding].”
31. *Supra* note 6, art. 11.
32. *Supra* note 6, art. 9.1a. This provision seems to be particularly geared towards the creation of SCNT embryos, which will purportedly eliminate the possibility of tissue rejection.
33. EGE, *supra* note 13 at 16-17, s. 2.7.
34. UNESCO, *supra* note 12 at para. 55.
35. *Supra* note 5, in Part I under the section entitled “Conclusion.”

36. *Supra* note 17 at 1, 9.
37. See F. Baylis, “Assisted Reproductive Technologies: Informed Choice” in *New Reproductive Technologies: Ethical Aspects, Vol. 1 of the research studies of the Royal Commission on New Reproductive Technologies* (Ottawa: Minister of Supply and Services Canada, 1993) 47 at 49.
38. *Supra* note 3, Schedule 3, s. 6.
39. *Supra* note 3, Schedule 3, s. 2(1)(c).
40. *Supra* note 3, Schedule 3, s. 3(1)(b).
41. United Kingdom, Nuffield Council on Bioethics, *Stem Cell Therapy: the ethical issues* (Discussion Paper, 6 April 2000), online: Nuffield Council on Bioethics <<http://www.nuffieldfoundation.org/bioethics/publication/stemcell/rep000000299.html>> (date accessed: 30 November 2001) at para. 23-25 [hereinafter *Stem Cell Therapy*].
42. *Supra* note 5 in Part I under the section entitled “From medically assisted reproduction to research on the embryo.”
43. *Supra* note 14 at 18, s. 2.10: “Free and informed consent is required ... from the donor ... [and] it is necessary to inform the donor (the woman or the couple) of the possible use of the embryonal cells for the specific purpose in question before requesting consent.” This is not without ambiguity, but suggests that only the people undergoing fertility treatment (not necessarily the gamete providers) need to give consent.
44. Canada, *Proceed with Care: Final Report of the Royal Commission on New Reproductive Technologies*, vol. 1 (Ottawa: Minister of Government Services of Canada, 1993) at 639 [hereinafter *RCNRTs*]; *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Supply and Services Canada, 1998) art. 9.1.
45. *NIH Guidelines*, *supra* note 8, s. II.A.2.e: “[i]nformed consent should have been obtained from individuals who have sought fertility treatment and who elect to donate human embryos in excess of clinical need for human pluripotent stem cell research purposes.” UNESCO, *supra* note 12 at para. 55(B): “both parental donors of embryos ... should have been given full information as to the implications of the research and have given their prior, free and informed consent.”
46. *Proposals for Legislation*, *supra* note 4, ss. 6(1), 8(1), and 6(3). Analogously, the *Embryos Bill*, *supra* note 6, provides that individuals may provide their gametes or embryos for research purposes (arts. 5 and 8, respectively), and “[a]dults ... can provide their gametes for the special production of embryos for ... the culturing of embryonic cells” under certain circumstances (art. 9(1)(a); see note 40 above). But, the question of who has the “authority to decide” when embryo providers consent to “the culturing of embryonic cells” (art. 8(1)(a)) from embryos that were

created with (at least in part) someone else's gametes (who did not consent to such an endeavor), is not clearly resolved.

47. See N.K. Reame, "Making Babies in the 21st Century: New Strategies, Old Dilemmas" (2000) 10:3 Women's Health Issues 152 at 155: to the list of factors that might influence a person's willingness to provide gametes, can be added "intention to donate or destroy embryos remaining after infertility treatment."
48. *E.g.*, *RCNRTs*, *supra* note 44 at 639.
49. *NIH Guidelines*, *supra* note 8, s. II.A.2.e.
50. *Proposals for Legislation*, *supra* note 4. Section 6(3) stipulates in order for an in vitro embryo to be donated for research purposes pursuant to s. 8(2), the donor must have "consented in writing to its use for that purpose." Presumably, regulations made pursuant to the proposed Act (s. 40(1)), will outline informed consent requirements in greater detail.
51. *NIH Guidelines*, *supra* note 8, s. II.A.2.c.
52. For an analysis of this logical error, see generally F. Baylis, "Human Embryonic Stem Cell Research: Comments on the NBAC Report" in S. Holland, K. Lebacqz & L. Zoloth, eds., *The Human Embryonic Stem Cell Debate: Science, Ethics and Public Policy* (Cambridge: MIT Press, 2001) 51.
53. C.B. Cohen, "Use of 'Excess' Human Embryos for Stem Cell Research: Protecting Women's Rights and Health" (2000) 10:3 Women's Health Issues 121 at 121.
54. See G.J. Annas, "Ulysses and the Fate of Frozen Embryos – Reproduction, Research, or Destruction?" (2000) 343:5 *New Engl. J. Med.* 373 at 375.
55. For instance, Geron Corporation announced on March 13, 2001, that the U.S. Patent Office has issued Patent No. 6,200,806, with claims directed to human embryonic stem cells. The patent is part of the embryonic stem cell intellectual property portfolio licensed to Geron by the Wisconsin Alumni Research Foundation (WARF). David J. Earp, Geron's vice president of intellectual property stated:

This patent includes claims to preparations of human embryonic stem cells and methods of isolating them. It further strengthens Geron's proprietary position in human embryonic stem cells... Our patent portfolio includes U.S. patents for primate and human embryonic stem (ES) cells and human embryonic germ (EG) cells, as well as over 50 patent applications pending around the world covering many aspects of human embryonic stem cell culture, production, differentiation and uses in cellular reprogramming.

Further information on Geron can be obtained at

<http://www.geron.com>.

56. See *e.g.*, L.S. Cahill, "Social Ethics of Embryo Stem Cell Research" (2000) 10:3 Women's Health Issues 131 at 135.
57. *HFE Act*, *supra* note 3, s. 24(3): the Act allows directions regarding "the keeping, by or on behalf of a person to whom a licence applies, of gametes or embryos in the course of their carriage to or from any premises" to be made, which could presumably include financial compensation for storage and transportation.
58. *Proposals for Legislation*, *supra* note 4, s. 5(1): "[n]o person shall purchase or offer to purchase sperm or ova from a donor or a person acting on behalf of a donor or advertise for the purchase of sperm or ova from a donor." *NHMRC Guidelines*, *supra* note 7, guideline 11.9: "[c]ommercial trading in gametes or embryos" is ethically unacceptable and should be prohibited.
59. *Proposals for Legislation*, *supra* note 4, ss. 2(a) and (b): "[n]o person shall ... purchase, offer to purchase, an in vitro embryo or any part of one; or ... sell, offer for sale or advertise for sale, an in vitro embryo or any part of one." *NIH Guidelines*, *supra* note 8, s. II.A.2.a: "[n]o inducements, monetary or otherwise, should have been offered for the donation of human embryos for research purposes." *EGE*, *supra* note 13 at 19, s. 2.17: "[e]mbryos as well as cadaveric foetal tissue must not be bought or sold not even offered for sale." *Embryos Bill*, *supra* note 6, art. 8.2: "[t]he provision [of embryos must be] ... free of charge." *NHMRC Guidelines*, *supra* note 7, guideline 11.9: "[c]ommercial trading in gametes or embryos" is ethically unacceptable and should be prohibited.
60. *Proposals for Legislation*, *supra* note 4, s. 10(c): "[n]o person shall, except under the authority of a licence issued under subsection 12(1) ... reimburse a person for any expenses incurred in the creation or maintenance of an in vitro embryo or in the transfer of an in vitro embryo." *NIH Guidelines*, *supra* note 8, s. II.A.1.e: "[payment cannot exceed] the reasonable costs associated with the transportation, processing, preservation, quality control and storage of stem cells."
61. *Proposals for Legislation*, *supra* note 4, s. 10(a): "[a donor may be reimbursed] for any expenses incurred in the course of donating any sperm or ovum."
62. *E.g.*, *NIH Guidelines*, *supra* note 8, s. II.A.2.e.v.
63. For a discussion of the motives of embryo providers, and the often overlooked influence of coercion, see F. Baylis, "Our Cells/Ourselves" (2000) 10:3 Women's Health Issues 140, particularly at 144.
64. L.P. Knowles, "Property, Progeny, and Patents" (1999) 29:2 *Hastings Center Report* 38 at 40.

65. *HFE Act*, *supra* note 3, s. 24(4): directions can be made authorizing “any person to whom a licence applies to receive gametes or embryos from outside the United Kingdom or to send gametes or embryos outside the United Kingdom.” *Proposals for Legislation*, *supra* note 4, s. 8(3): “[n]o person shall, except under the authority of a licence issued under subsection 12(1), collect, store, transfer, destroy, import into Canada or export from Canada any sperm, ovum or in vitro embryo.”
66. *Supra* notes 24-26 and accompanying text.
67. *Stem Cell Therapy*, *supra* note 41 at para. 39: “[w]e recommend that the granting of overgenerous patents with broad claims in this important field should be discouraged.” Reference is also made to an earlier report, Nuffield Council on Bioethics, *Human Tissue: Ethical and Legal issues* (1995), online: Nuffield Council on Bioethics <<http://www.nuffieldfoundation.org/bioethics/publication/pub0000000308.html>> (date accessed: 30 November 2001), which includes the following statement at para. 13.40: “[w]e recognise that inventions derived from human tissue are open to patenting ... We accept this position as a matter of fact.”
68. *Supra* note 13 at 14, s. 2.1.
69. See, among others, Knowles, *supra* note 64 at 40.
70. See preamble to the Canadian *Proposals for Legislation*, *supra* note 4.
71. Knowles, *supra* note 64 at 40.
72. T. Caulfield, E.R. Gold & M.K. Cho, “Patenting human genetic material: refocusing the debate” (2000) 1 *Nature Reviews Genetics* 227 at 230.
73. *Ibid.*
74. *NIH Guidelines*, *supra* note 6, s. II.A.2.d: “[d]onation of human embryos should have been made without any restriction or direction regarding the individual(s) who may be the recipients of transplantation of the cells derived from the embryo.”
75. *Supra* note 13 at 19, s. 2.14: a prohibition of directed donation can be inferred from the statement that: “the donor should not know the identity of the recipient, nor should the recipient know the identity of the donor.”
76. *HFE Act*, *supra* note 3: s. 4(1)(c) prohibits the mixing of gametes with the live gametes of any animal *except in pursuance of a licence*. To that effect, Schedule 2 allows a licence to be granted in the course of treatment services or for research purposes, to mix sperm with egg of a hamster, or other animal specified in directions, for the purpose of testing the fertility or normality of the sperm, but only where anything which forms is destroyed when the test is completed and, in any event, not later than the two cell stage (paragraph 1(1)(f) and 3(5) respectively). These provisions are qualified by s. 24(11) which stipulates that where the HFEA proposes to give directions specifying any animal for the purposes of paragraphs 1(1)(f) or 3(5), they must first be reported (not necessarily approved by) to each House of Parliament.
- Stem Cell Therapy*, *supra* note 41 at para. 35 recommends “that the HFEA seek clarification of the regulatory status of this kind of research in the UK” and then consider amending the *HFE Act*. Similarly, the so-called “Donaldson Report” (United Kingdom, Chief Medical Officer’s Expert Group to the Department of Health, *Stem Cell Research: Medical Progress with Responsibility* (2000), online: Department of Health <<http://www.doh.gov.uk/cegc/stemcellreport.htm>> (date accessed: 30 November 2001) at 47 recognizes that “[t]he 1990 Act does not control the mixing of animal eggs with other human cells” and that “[a] new Act of Parliament would be required to implement [Recommendation 6].” Recommendation 6 states: “[t]he mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted.”
77. *NIH Guidelines*, *supra* note 8, s. III.F: “[r]esearch in which human pluripotent stem cells are combined with an animal embryo [is ineligible for NIH funding].” *Embryos Bill*, *supra* note 6, art. 25(a): “[c]ombining a human and an animal gamete with a view to generating a multicellular hybrid [is prohibited].” *DFG Statement*, *supra* note 16, s. II.2: “[the DFG supports] the prohibition to create human beings with artificially altered genomes, such as germ line intervention or formation of chimaeras or hybrids.” *NHMRC Guidelines*, *supra* note 7, guideline 11.5: “[m]ixing of human and animal gametes to produce hybrid embryos [is prohibited].”
78. *Proposals for Legislation*, *supra* note 4, ss. 9(1) and (2).
79. *Stem Cell Therapy*, *supra* note 41 at para. 42, considers that: “[i]n the early stages of stem cell research it would be useful to have some form of control or oversight ... Proposed uses of stem cells could be considered within the Department of Health alongside other therapies. One proposal is that the HFEA’s remit should be extended to cover responsibility for stem cell lines ... An alternative would be to consider the expansion of the remit of the Gene Therapy Advisory Committee (GTAC) to include the therapeutic non-reproductive use of stem cell lines.”
80. *NIH Guidelines*, *supra* note 6, s. IV: the Human Pluripotent Stem Cell Review Group (HPSCRG). Since that time, the HPSCRG has come into existence but its present status is shaky: see *e.g.* G. Vogel, “NIH Pulls Plug on Ethics Review” (2001) 292 *Science* 415a.

81. See “Text: Bush’s Address on Stem Cell Research” *The New York Times* (10 August 2001) online: New York Times <<http://www.nytimes.com>> (date accessed: 14 August 2001).
82. Health Canada, *Proposals for Legislation Governing Assisted Human Reproduction: An Overview* (2001) at 9.
83. CCNE, *supra* note 5 in Part I under the section entitled “Creation of APEGH”: “[the] CCNE approves the creation of the future Human Reproduction, Embryology, and Genetics Authority (Agence de la procréation, de l’embryologie et de la génétique humaines – APEGH) as set out in the preliminary draft [subject to some minor changes]. It sees as pertinent, in particular, that APEGH’s tasks should not exclude the ethical dimension of issues it will be dealing with, since such a dimension appears to be so closely linked to their scientific, legal, social, and possibly economic, aspects.”
84. *Embryos Bill*, *supra* note 6, art. 3(2): “[t]he research [with embryos] shall only be permitted if a positive opinion about the research protocol is received from the Central Committee.” *Embryos Bill Brochure*, *supra* note 15 at 11: “[a] national ethics committee – the Central Committee on Research involving Human Subjects (CCMO) – must examine the research plan (the protocol) in advance.” Presumably, the CCMO would oversee any research involving the derivation and use of ES cells since it already safeguards research involving embryos.
85. UNESCO, *supra* note 9 at para. 55(A), “urges that debates be conducted at appropriate regulatory levels” and that “[s]tates should take appropriate measures to initiate an on-going dialogue within society on the ethical issues raised by such research, involving all actors concerned.” It is therefore apparent that UNESCO would support oversight and some form of national regulation, as each nation saw fit.
86. EGE, *supra* note 13 at 16, s. 2.6: “[a]ccording to the Group, it is crucial to place ES cell research, in the countries where it is permitted, under strict public control by a centralized authority.”
87. *DFG Statement*, *supra* note 16, s. II.3: “[endorses] the establishment of a central commission which would have to assess research projects with EG cells or ES cells on the basis of ethical, legal, and scientific point of views and which would function also as a supervisory attendant body.”
88. For a discussion of a report, not discussed herein, which arguably takes this approach, see G. Meilaender, “The Point of a Ban: Or, How to Think about Stem Cell Research” (2001) 31:1 *Hastings Center Report* 9 at 14.
89. 793 P.2d 479 (Cal. 1990) cert. denied 111 S.Ct. 1388.
90. G. McGee & A. Caplan, “The Ethics and Politics of Small Sacrifices in Stem Cell Research” (1999) 9:2 *Kennedy Institute of Ethics Journal* 151 at 153.
91. For an interpretation of the NBAC report, which opines that this is NBAC’s underlying position, see Meilaender, *supra* note 88 at 14.

