Chapter 6
Policy Design for Human Embryo Research in Canada: 1989–2015

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Introduction

In Canada, research involving in vitro human embryos is circumscribed by law promulgated by the federal Parliament and research guidelines issued by the Tri-Agencies: the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). To be precise, the use of human embryos is governed by the Assisted Human Reproduction Act, S.C. 2004, c.2 (hereafter *AHR Act*), which prohibits some types of human embryo research under threat of criminal sanction (maximum penalties are a fine of $500,000, 10 years imprisonment, or both). As well, human embryo research is governed by the *2nd edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (hereafter, *TCPS2*) (CIHR et al. 2014).

Unlike the *AHR Act*, which covers both publicly- and privately-funded embryo research, the *TCPS2* only governs federally-funded researchers and their institutions. As a condition of funding, researchers are expected to adhere to the *TCPS2* and institutions that receive Agency funding must sign an Agreement with the

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CIHR, NSERC and SSHRC certifying compliance with the *TCPS2* (Agreement 2013). Where the *AHR Act* and the research guidelines overlap, the *AHR Act* takes precedence; where the *AHR Act* is silent, the research guidelines set the standard for federally-funded research.

There are two parts to this chapter. The first part provides a chronological description of policy developments related to human embryo research in Canada over the past 25+ years, with particular attention to efforts at public consultation. We begin with a review of the policy processes leading up to, and following on from, the promulgation of the *AHR Act* (see also, Norris and Tiedemann 2015). We then review the development and introduction of the *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (CIHR 2002) as revised in 2005, 2006, 2007, and 2010 and finally integrated into the TCPS 2 chapter 12, section F in December 2014. We do not review the history of the *TCPS2* given the broad scope of these research guidelines. We do, however, include information on the substance of these guidelines where relevant. The second part of the chapter critically examines the history of policy design for human embryo research in Canada, applying a typology of modes of public consultation developed by Eric Montpetit (2003). Our effort to better understand the various episodes of policy design and their corresponding outcomes reveals a depreciating linkage between policy development related to human embryo research and the input of Canadians through public consultation.

Policy Design for Human Embryo Research in Canada: A Brief Chronology (Table 6.1)

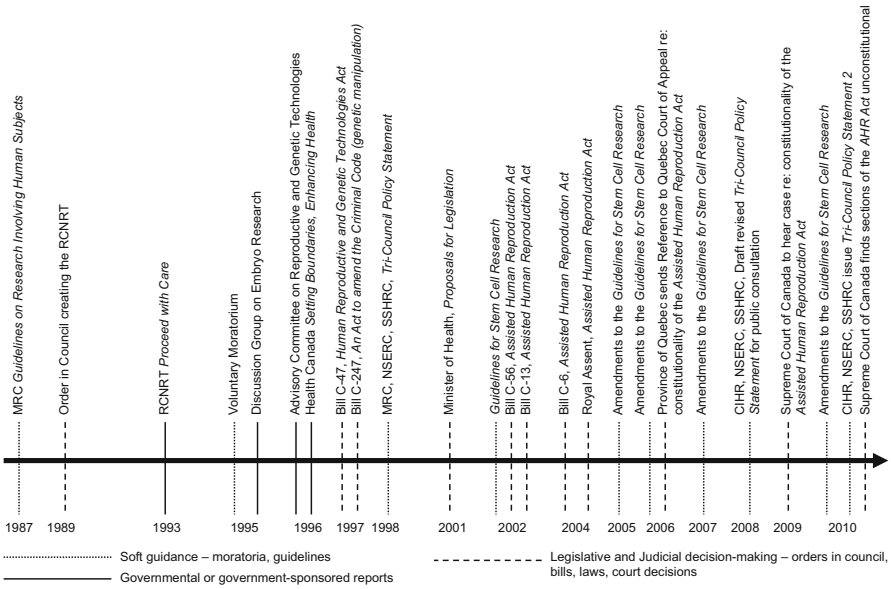
From the Royal Commission to the AHR Act

On October 25, 1989, following a couple of years of intense lobbying, Canada's Royal Commission on New Reproductive Technologies (RCNRT 1990) (hereafter the Royal Commission) was announced (Roberts 1999). The Commissioners represented the fields of medicine, law, religion, and sociology. The Royal Commission's explicit mandate was to,

> inquire into and report on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied. (RCNRT 1993, 3)

The Royal Commission had two overarching tasks: to provide an opportunity for public involvement in policy design; and to assess the relevant medical and scientific developments (Massey 1993). In planning for public participation, the Royal Commission "set up an extensive Public Consultation Program to give Canadians from all walks of life and from all regions of the country the opportunity to contribute to the work, as it studie[d] the origins, effects and impacts of the technologies" (RCNRT 1990, 3).

Table 6.1 Summary of Canadian policy development related to human embryo research



The final report spanned two volumes and contained 293 policy recommendations. Although the financial cost was significant (according to Montpetit $28 million (2003)), the Royal Commission's efforts to raise awareness of its work and the issues, to stimulate conversation and debate at the community level, and to receive input from Canadians were unprecedented. In total, over 40,000 Canadians "participated in clinical studies and national surveys, attended Public Hearings and Private Sessions, sent letters of opinion and written submissions, or left their thoughts on […] toll-free telephone lines" (RCNRT 1992, 1) (see Appendix 6.1). On the basis of this public consultation effort, the Royal Commission reported a "consistent and widespread demand for national leadership and action in relation to [new reproductive technologies]" (RCNRT 1993, 11).

In its final report, *Proceed with Care*, the Royal Commission recommended that the Canadian government develop a comprehensive legislative response to new reproductive technologies, including human embryo research (RCNRT 1993). (See Appendix 6.1) At the time, the Medical Research Council of Canada *Guidelines on Research Involving Human Subjects* provided three basic parameters around when, why, and what types of human embryos could be used in research (MRC 1987, 35). In contrast, the Royal Commission provided considerable more detail and specifically recommended that research on embryos be "restricted to the first 14 days of development"; that embryo research related to "ectogenesis, cloning, animal/human hybrids, and the transfer of zygotes to another species be prohibited, under threat of criminal sanction"; that "clinics and researchers be permitted to use human zygotes for research only with the fully informed consent of the persons who have donated

the gametes used to create the zygote"; and that a "woman's or couple's consent to donate zygotes generated but not used during infertility treatment for research never be a condition, explicit or implicit, of fertility treatment" (RCNRT 1993, 636–37, 639, and 640, Recommendations 183, 184, 186, and 187, respectively). The Royal Commission also recommended that embryo research be subject to licensing requirements (RCNRT 1993, 645, Recommendation 193).

In the spring of 1994, the Health Policy Division, Policy and Consultation Branch of Health Canada initiated a consultation on the findings of the Royal Commission with over 50 stakeholders from groups as diverse as disabled communities and anti-abortionists (Health Canada 1996b, 14). The predominant views in Canada at that time reflected competing beliefs about the moral status of the developing human embryo. For some, the human embryo had near-person status. For others, the human embryo was a mass of tissue that did not deserve special protections.

In April 1995, Health Canada established a nine-member multidisciplinary Discussion Group on Embryo Research (hereafter Discussion Group) "to propose logically, ethically, and socially justifiable policy in this area" (Discussion Group 1995, 36), and more specifically to address the following question: "Should experimentation on human embryos, including pre-implantation diagnosis, be permitted in Canada?"

In July 1995, while the work of the Discussion Group was in midstream, then-Minister of Health Diane Marleau announced a voluntary interim moratorium on nine new reproductive and genetic technologies, many of which (directly or indirectly) concerned embryo research. Practices governed by the interim voluntary moratorium included: sex-selection for non-medical purposes; commercial pre-conception or "surrogacy" arrangements; buying and selling of eggs, sperm, and embryos; egg donation in exchange for in vitro fertilization (IVF) services; germline genetic alteration; ectogenesis (creation of an artificial womb); the cloning of human embryos; formation of animal-human hybrids by combining animal and human gametes; and the retrieval of eggs from cadavers and foetuses for donation, fertilization or research (Health Canada 1995; Health Canada 1996a). At the same time the voluntary interim moratorium was announced, the federal government outlined its plan to develop regulations for sperm donation (for artificial insemination and in vitro fertilization), and to develop (in consultation with the provinces and territories) a comprehensive legislative framework for new reproductive and genetic technologies.

The Discussion Group submitted its final report in November 1995. It concluded that embryo research should be permitted in Canada and issued 20 policy recommendations (see Appendix 6.2), all of which assumed that a National Regulatory Body would be created to approve and oversee human embryo research (Discussion Group 1995, 2).

In January 1996, amidst concerns about the degree to which researchers and clinicians were conforming to the voluntary interim moratorium, an Advisory Committee on the Interim Moratorium on Reproductive and Genetic Technologies (soon after renamed the Advisory Committee on Reproductive and Genetic Technologies) was created to monitor compliance and advise the federal govern-

ment. Later that same year, in June 1996, the prohibitions bill was introduced into the House of Commons by then-Minister of Health David Dingwall. Bill C-47 the *Human Reproductive and Genetic Technologies Act* aimed to reflect "the views of Canadians that certain practices are unacceptable and violate the principles of human dignity" (Health Canada 1996b, 6). The Bill prohibited, under threat of criminal sanction, 13 discrete practices, including all of the practices listed in the voluntary interim moratorium. At the same time the Bill was tabled, Health Canada published *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (hereafter *Setting Boundaries, Enhancing Health*). This document outlined the government's two-part legislative plan: "outright prohibition of unacceptable technologies through legislation; and development of a legislated regulatory regime to manage acceptable technologies" (Health Canada 1996b, 5). This document was to inform the next consultation phase.

Before the legislative process for Bill C-47 was completed a federal election was called, and the bill died on the order paper. After Parliament reconvened in the fall of 1997, Health Canada was instructed to undertake new public consultations on the basis of which new legislation could be drafted.

In May 2001 then-Minister of Health Alan Rock presented the House of Commons Standing Committee on Health with *Proposals for Legislation Governing Assisted Human Reproduction* (Health Canada 2001). A year later, in May 2002, comprehensive legislation on new reproductive technologies, Bill C-56, *An Act respecting assisted human reproduction* was introduced in the House of Commons. Notably, parts of Bill C-56 overlapped with the *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* introduced in March 2002 by CIHR (Baylis 2002). This Bill, which aimed to establish a legislative and regulatory framework for assisted human reproduction and embryo research, also died on the order paper when Parliament was prorogued in September 2002. When Parliament resumed in October 2002, Bill C-56 was reinstated as Bill C-13 at the same stage in the legislative process as prior to prorogation—this had not happened with the previous bill (Bill C-47). On March 11, 2004, Bill C-6 (formerly Bill C-13) completed all legislative stages. On March 29, 2004 the *AHR Act* received Royal Assent bringing to an end 15 years of policy development (Health Canada 2008).

In 2006, however, the Government of Québec filed a reference with the Québec Court of Appeal challenging the constitutionality of several sections of the *AHR Act* (Attorney General of Québec 2006). The Québec government argued that health was a provincial responsibility. The federal government insisted that the *AHR Act* was a valid exercise of its authority to act to safeguard morality, safety, and public health.[1] In June 2008, the Québec Court of Appeal opined that the federal government did not have the constitutional authority to legislate this (and other) provisions under its criminal law power. In August 2008 the Attorney General of Canada filed an appeal to the Supreme Court of Canada (SCC). On April 29, 2009 the SCC heard the appeal and on December 22, 2010 released its decision (Reference re *Assisted*

[1] Françoise Baylis prepared an expert opinion for the federal government in relation to the Québec reference (see, Baylis 2006).

Human Reproduction Act 2010 SCC 61). The SCC held that some of the contested sections, including section 10, which governs the use of in vitro embryos, were unconstitutional (Baylis 2011). Because the case was initiated by a reference from the Québec government, the SCC's decision was advisory rather than legally binding. No provincial or federal government in Canadian history, however, has ignored an SCC advisory decision in a reference case. In 2012, the federal government made significant changes to the *AHR Act*, some of which aimed to implement the SCC's decision (*An Act to implement the certain provisions of the Budget* 2012).

Notably, the constitutional challenge did not affect the prohibited activities: human cloning; creating an embryo for research (except for the limited purpose of improving or providing instruction in assisted human reproduction procedures); creating an embryo from an embryo or a fetus; maintaining an embryo in vitro for more than 14 days; purchasing gametes, embryos; creating or transplanting a chimera made from a human embryo; creating a hybrid for the purpose of reproduction; using reproductive material without consent; and obtaining gametes from a donor under the age of 18 except for the purpose of preserving the sperm or ovum or for the purpose of creating a child to be raised by the donor(s). All of these remained legally prohibited activities in Canada (see Appendix 6.3).

Guidelines for Research Involving Human Embryos

The 1st edition of the *TCPS* (the Canadian guidelines governing research involving humans) came into effect in 1998 (MRC et al. 1998), before James Thomson and John Gearhart announced their respective successes in deriving human pluripotent stem cells (Thomson et al. 1998; Shamblott et al. 1998). These guidelines stipulated in Article 9.4 that:

> It is not ethically acceptable to create human embryos specifically for research purposes. However, in those cases where human embryos are created for reproductive purposes, and subsequently are no longer required for these purposes, research involving human embryos may be considered to be ethically acceptable but only if all of the following apply:
>
> (a) The ova and sperm from which they were formed are obtained in accordance with Articles 9.1 and 9.2;
> (b) The research does not involve the genetic manipulation of human gametes or embryos;
> (c) Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and
> (d) Research involving human embryos takes place only during the first 14 days after their formation by combination of the gametes. (MRC et al. 1998, 75)

At the time, in the absence of explicit Canadian policy or law on human embryonic stem cell (hES cell) research, in late 2000, the CIHR struck an *ad hoc* Working Group on Stem Cell Research (hereafter Working Group). This nine-member group

included six scientists/clinicians (one of whom was Chair), two philosophers (one of whom was Françoise Baylis), and one lawyer (CIHR WG 2001). Amidst a slew of governmental and quasi-governmental reports trumpeting the promises of hES cell research but tempered, to varying degrees, by the attendant ethical concerns (Chapman et al. 1999; NBAC 1999; United Kingdom 2000; Vogel 2000), the Working Group was mandated to evaluate whether CIHR should fund research to derive and study human pluripotent stem cells and, if so, under what conditions.

On March 29 2001, the CIHR initiated a three-month public consultation on a Discussion Paper prepared by the Working Group, *Human Stem Cell Research: Opportunities for Health and Ethical Perspectives* (CIHR WG 2001). There was a national press conference announcing the electronic publication of this document on the CIHR website. As well, the document was disseminated electronically to all CIHR-funded institutions (which essentially includes every academic research institution in Canada). There were 116 responses to the Discussion Paper: 89 from individuals and 27 from "special interest groups, professional groups, health charities, [and] governmental agencies" (CIHR WG 2002). "Many" of these responses highlighted concerns about the moral status of the human embryo, the need to utilize adult stem cells instead of embryonic or foetal stem cells, the potential coercion of couples involved in fertility treatment(s) or women undergoing therapeutic abortion, the slippery slope to cloning and eugenics, and the lack of governance for private sector research. "Some" of these responses expressed concern about likely research delays resulting from the introduction of an oversight mechanism, the skewed composition of the Working Group (too many scientists and no lay representation), and the ambiguity of the term "moratorium" in the Discussion Paper. Finally, a "few" respondents noted that CIHR's chosen medium of consultation—the web—precluded certain segments of society from participating in the process (CIHR WG 2002).

On March 4 2002, with the legislative process for the *AHR Act* underway, the CIHR released its guidelines entitled *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research* (CIHR 2002). The guidelines stipulated that research to derive and study human pluripotent stem cell lines from embryos, fetal tissue, amniotic fluid, the umbilical cord, placenta, and other body tissues (either from persons or cadavers) was eligible for funding, but that research involving the creation of human embryos for research purposes, the use of somatic cell nuclear transfer to develop stem cell lines, the mixing of human or non-human stem cells with a human embryo or fetus, and the mixing of human stem cells with a non-human embryo or fetus was not eligible for funding.

Until June 2005 there were no revisions to the original 2002 *Human Pluripotent Stem Cell Research: Guidelines for CIHR-Funded Research*. At that time, and again in 2006, 2007, and 2010 revisions were recommended by the CIHR Stem Cell Oversight Committee (SCOC) and approved by the three federal funding Agencies (CIHR, NSERC and SSHRC). The approval was by the three federal funding Agencies because, as of 2005, the guidelines applied "to all research involving human pluripotent stem cells that is funded by the Agencies, or is conducted under the auspices of an Institution that receives any Agency funding" (CIHR 2005b).

Unfortunately, the initial (albeit limited) effort at public consultation in drafting the original 2002 stem cell guidelines did not have a precedent-setting effect. Successive revisions to these guidelines in 2005, 2006, and 2007 were all made without the benefit of public consultation. Breaking with that tradition, in October 2007 the CIHR SCOC initiated a four-month online consultation (from October 19, 2007 to February 15, 2008) concerning Section 5 of the 2002 Guidelines. Section 5 ("Creating a national registry") promised that CIHR would "establish an electronically accessible national registry of human embryonic stem cell lines generated in Canada" (CIHR 2002). Such a registry was intended to "minimize the need to generate large numbers of stem cell lines, which should decrease the need for donation of large numbers of embryos" (CIHR 2002). The 2007, four-month online consultation asked whether all human pluripotent stem cell lines derived under the auspices of an institution that receives Agency funding must be listed with the registry, or whether the inclusion rule should only be applied to lines created using Agency funds. (Further explanation given below).

There were no revisions to the stem cell guidelines in 2008 or 2009. Then, in June 2010, two major changes were introduced. First, the SCOC's purview was extended to include oversight of research involving induced human pluripotent stem cells (iPS cells) (CIHR 2010). Second, following on the 2007–2008 online public consultation, the scope of the national stem cell registry was clarified to specify that human iPS cell lines would not be listed in the registry, but that all other "human pluripotent stem cell lines derived directly from embryos under the auspices of an institution that receives any Agency funds must be listed with the registry and made available by the researcher to other researchers, subject to reasonable cost-recovery charges" (CIHR 2010).

Later that same year (2010), the *TCPS2* was published. This was the first time in 12 years that the guidelines for research involving humans were significantly revised (prior to this, only minor amendments were introduced in 2000, 2002, and 2005). Given that the incorporation of the stem cell guidelines into the *TCPS* was promised in the 2003 *Interim Tri-Agency Measures for Human Pluripotent Stem Cell Research* (and repeatedly referenced thereafter in successive versions of the *Updated Guidelines for Human Pluripotent Stem Cell Research* (2005, 2006, 2007, and 2010)), it was expected that the Panel on Research Ethics (the organization responsible for revisions to the 1st edition of the *TCPS*) would put an end to the ethical exceptionalism in the oversight of hES cell research in Canada (Baylis and Downie 2011, 2012). This was not to be the case, notwithstanding the fact that at least some of the public consultations on revisions to the *TCPS* were at pains to underline this long-standing commitment (e.g., Baylis 2009, 2010).

While the *TCPS2* did not include guidelines on research involving human pluripotent stem cells, it did include minor revisions to the guidelines for research involving human embryos. The current guidelines stipulate in Article 12.8 that:

> Research involving embryos that have been created for reproductive or other purposes permitted under the *Assisted Human Reproduction Act*, but are no longer required for these purposes, may be ethically acceptable if:

(a) the ova and sperm from which they are formed were obtained in accordance with Article 12.7;
(b) consent was provided by the gamete donors[2];
(c) embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and
(d) research involving embryos will take place only during the first 14 days after their formation by combination of the gametes, excluding any time during which embryonic development has been suspended. (CIHR et al. 2010, 184)

It would take another 4 years, before the three federal funding Agencies would make good on their promise to incorporate the stem cell guidelines into the *TCPS*. Only in December 2014, after many years of lobbying on the part of some scholars (including Baylis 2009, 2010; Baylis and Downie 2011, 2012), were the stem cell guidelines finally integrated into the revised *TCPS2* (CIHR et al. 2014). According to the official record, this change was motivated by a desire "to unify all Agency guidance on the ethics of human research into one document" (CIHR 2014a). Notably, however, whereas the rules governing human pluripotent stem cell research now appear in the same document as the rules for all research involving humans, the authority to develop, interpret, and implement these rules rests with a separate oversight body—namely, CIHR's SCOC. For all other research involving humans, this responsibility rests with the Panel on Research Ethics. As CIHR explains on its website, the

> SCOC will continue to provide ongoing review of the relevant section of TCPS 2 (2014), chapter 12, section F to ensure continuing relevance, submitting its recommendations to the CIHR Governing Council. Governing Council would then submit its endorsed recommendations to the Panel. The Panel would then submit proposed revisions to the three Agencies (CIHR, NSERC & SSHRC) for review and approval by their Presidents. (CIHR 2014a)

As we detail in the second part of this chapter, the problematic revisions to the *Updated Guidelines for Human Pluripotent Stem Cell Research* and the *TCPS2* dovetail with a troubling trend in policy design for human embryo research—namely, the diminishing participation in policy development by Canadians. As best we can discern, of late, Canadians who are not members of special interest groups or policy communities have been spoken for, rather than spoken with, in matters relating to the oversight of human embryo research. We show this by reinterpreting the foregoing history of embryo research policy development through a typology of modes of public consultation developed by Montpetit (2003).

[2] For a critical review of consent forms used by researchers who provided hES cell lines approved for use by CIHR, see Krahn and Wallwork (2011).

Policy Design for Human Embryo Research in Canada: A Brief Analysis

Legitimacy in policy design depends, in large measure, on achieving the right balance between output-oriented legitimacy and input-oriented legitimacy. In very general terms, output-oriented legitimacy is usually expertise-based, while input-oriented legitimacy is always citizen-centered. Or, following Montpetit, "[o]utput-oriented legitimacy is conferred onto public policies to the extent that they are viewed as enhancing the public good, independently of who has conceived them. To obtain such policies, policymakers have traditionally relied on experts" (Montpetit 2003, 97). Conversely, "[i]nput-oriented legitimacy…depends on the extensiveness and intensiveness of public participation in the making of policy. Legitimacy here is conferred upon policies when a large public feels it has been consulted and heard" (Montpetit 2003, 97).

In a helpful analysis of policy design for assisted human reproduction in Canada, Montpetit looks beyond the variety of instruments available for public consultation (e.g., advisory committees, focus groups, sequential consultations, consensus conferences, information-technology-supported dialogues or surveys, citizen juries, and toll-free numbers), to critically examine the institutional and cultural contexts in which these instruments are used in pursuit of input-oriented legitimacy for public policies (Montpetit 2003). From an input-oriented legitimacy perspective, "[p]olitical choices are legitimate if and because they reflect the 'will of the people'–that is, if they can be derived from the authentic preferences of the members of a community" (Scharpf 1999, 6).

Input-oriented design processes require public involvement and as such they have a higher potential than output-oriented design processes to reduce the legitimacy deficit (Montpetit 2008). But this potential comes at a price. Public policy consultation can be difficult–cumbersome, confusing, time-consuming and expensive – particularly if there is a genuine commitment to diversity, where the goal is not only to hear from more people (i.e., a wider array of individuals), but also to hear from more standpoints (i.e., a wider array of ideas).

Montpetit defines three triangulated modes of public policy consultation–consultation conducted in a mode of communicative action, strategic consultation, and rule-guided consultation. In turn, he explains how each of these modes of consultation characterizes a particular style of political interaction between those who are responsible for public policy consultation and those who are consulted.

With communicative action as the mode of public policy consultation, genuine dialogue and deliberation are the hoped-for modes of interaction. Those responsible for public consultation and those consulted may have preconceived ideas and preferences about what policies should be generated, but they are willing to set them aside and to learn from each other, as a means to the end of better policy development. According to Montpetit, "[p]ublic consultations here are neither strategic instruments nor mere obligations in the policy design process, but rather, opportunities to argue in pursuit of unforeseen ideas to resolve policy problems" (Montpetit

2003, 101). As Montpetit, Scharpf, and others concede, however, a problem-solving orientation to policy design is a most rare occurrence because it requires of policy designers that they accept challenges to their preferences and give up control over the outcome of the public consultation process. In short, it requires a commitment to genuine discourse and this may not always be feasible or desirable.

With strategic consultation, those who are responsible for policy design and who initiate the public consultation have clear policy preferences for which they are seeking input-oriented legitimacy. In this instance, the goal of public dialogue is not to generate policy options, but rather to effectively communicate policy preferences and persuade those who are consulted to support the preferred policy option.

With rule-guided consultation, the principal aim is to satisfy political obligations, as when politicians demand public consultation in an effort to increase the input-oriented legitimacy of the policies they intend to promulgate. This mode of public consultation may or may not have an impact on the original policy intent and orientation, depending upon the fit between the preferences of the civil servants directed to undertake the consultation and the publics that are consulted.

Here we re-canvass the various policymaking exercises on human embryo research undertaken by the federal government and the CIHR over the last 25+ years using Montpetit's framework.

Communicative Action and the Law on Embryo Research

In Canada, the legislative process that ends with the introduction of the *AHR Act* in 2004 begins with the Royal Commission in 1989. The Royal Commission's mandate, as outlined in the Order in Council did not explicitly name "identifying the views and values of Canadians" among its objects. It is nonetheless clear that the Royal Commission regarded this as integral to its investigative methodology, ethical analysis, and final output. This, in part, owes to the nature of Royal Commissions established under the federal *Inquiries Act*, R.S.C. 1985, c. I-11, and the function that Royal Commissions have historically performed in Canada (Massey 1993).

According to Montpetit, the Royal Commission was an opportunity ripe for communicative action. Indeed, some 40,000 Canadians contributed to the Royal Commission's work. While some complain that this number is misleading insofar as it includes some 15,000 survey respondents in the rate of public participation (Massey 1993, 245), current lore and government policymakers certainly have it that the Royal Commission succeeded in articulating "Canadian values".

Critics insist, however, that the Royal Commission failed to achieve communicative action owing, in part, to the inherent limitations of public hearings as a technique of public participation, and the nature of the deliberations among Commissioners.

First, the centerpiece of the public consultation effort undertaken by the Royal Commission was the public hearing. According to Christine Massey, there are a

number of serious weaknesses with this technique relative to the goal of public engagement:

> Some of the most common drawbacks are: procedural rules which make it difficult to initiate two-way communication; intervenors who are not representative of the total population; and the lack of impact on the final decision. Abuses to which the public hearing lends itself are: a habit of inadequate notification; the selective or elite involvement in the hearings; and an overemphasis on providing information rather than receiving it. (Massey 1993, 238)

Of particular concern among this list of weaknesses is the fact that royal commissions typically privilege the powerful:

> … commonly, royal commissions give voice and legitimacy to those groups in our society who already have it. While all intervenors may officially be equals in the hearings process, those with financial and/or legal interest in the issue tend to be given greater status. Advocacy groups, especially those with more diffuse memberships, suffer most. (Massey 1993, 239)

With specific reference to the Royal Commission the record shows that professional organizations, especially those representing the scientific and medical communities, were able to engage more effectively in the public hearing process than women's advocacy groups. In part, this is because no collective voice emerged to represent the full diversity of women's views.

Second, with regard to the nature of the deliberations among Commissioners, Janet Hatcher Roberts (past-Deputy Director of Research and Evaluation for the Royal Commission) reports that there was considerable mistrust among the Commissioners along the axis of medical bias:

> Concepts such as "weight of evidence," relative effectiveness, and meta-analysis were considered suspect because some Commissioners felt they were driven by medical models of evaluation. … while to a certain degree their questioning was relevant, significant effort was given to social, feminist analysis of these issues and to integrate this analysis with the other medical, social, and economic analyses. Yet, the polarization remained and in fact became more pronounced as the Commission did its work. (Roberts 1999, 20)

Part way through the Royal Commission's deliberations four Commissioners filed a lawsuit against the Royal Commission and the Canadian government alleging a flawed public engagement process and an unclear research agenda (Roberts 1999). These Commissioners were fired, as a result of which they lost their standing before the court, and the lawsuit was dropped. Two new Commissioners were appointed and the reconstituted Royal Commission went on to publish a comprehensive set of recommendations.

Now, according to Montpetit, truth-seeking is a feature of public consultation in the mode of communicative action, and so the question arises: were the Commissioners genuinely "prepared to put their preferences on the back burner for the sake of truth-seeking … [in an effort to identify] the best possible policy solution for the problem at issue?" (Montpetit 2003, 101). Arguably, this question cannot be answered authoritatively except by individual Commissioners who can speak to their willingness (or not) to entertain challenges to their ideas and preferences.

However, the Royal Commission's troubled history suggests that the answer to this question may be "no".

Strategic Consultation and the Law on Embryo Research

Between the publication of the Royal Commission's final report *Proceed with Care* (RCNRT 1993) and the publication of Health Canada's paper *New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health* (Health Canada 1996b) outlining the planned federal legislation, a strategic public consultation was undertaken by the federal government to validate the Royal Commission's recommendations. With this second wave of consultations, unlike the previous one undertaken by the Royal Commission, there were clear and somewhat fixed policy preferences, namely the policies recommended by the Royal Commission. As Montpetit explains,

> Several officials of the Health Policy Division responsible for ART policy design after 1993 were either close to the Royal Commission, or actual former employees of the commission. It was therefore difficult for the Health Policy Division to accept challenges to the … recommendations for limited prohibitions of ART practices and for the establishment of a regulatory commission to oversee standing practice – when so much effort and money had been invested in them. (Montpetit 2003, 105)

While the strategic public consultation undertaken at this time revealed considerable disagreement between various interest groups (researchers and the medical profession, consumers, women's groups, pro-life groups and the provinces), Health Canada concluded that the Royal Commission's findings were valid. It acknowledged, however, a need for additional consultation on embryo research and a need for further consultation with the provinces and territories. A Discussion Group on Embryo Research was established in April 1995 and its final report was issued in November 1995 (Discussion Group 1995). Subsequently, Health Canada published *Setting Boundaries, Enhancing Health* and Canadians were invited to provide written comments on the proposed legislated regulatory regime. However, as reported by Montpetit, at this point in the process at least some Health Canada officials were not keen on further public consultation:

> It was basically the government's position paper. That was the government thing: we looked at all the stuff, we talked to all these people, this is now what we're going to do. Some people within government would refer to it as a discussion paper, and I'd say, "no, we've discussed, we're finished discussing. This is what we're going to do, we're going to pass legislation, and it's going to look like this." And so it was [Bill C-47]. (Montpetit 2003, 106)

Rule-Guided Consultation and the Law on Embryo Research

After Bill C-47 died on the order paper and Parliament was reconvened in the fall of 1997, staff members at Health Canada were instructed to consult with the Canadian people on the matter of assisted human reproduction so that their views could inform the drafting of a new bill. Staff in the Health Policy Division of Health Canada, however, considered further public consultation unnecessary as evidenced by the limited consultation that followed in 1999. What little public consultation took place had a limited objective: to satisfy a government directive. No doubt, for some, a certain amount of policy design fatigue had set in and there was little (or no) desire to hear from, or even persuade, Canadians. Meanwhile, many Canadians expressed increasing frustration with the ongoing delays in acting on the recommendations of the Royal Commission.

For reasons that are not clear, the public consultation task was moved from the Health Policy Division of Health Canada to a special project division. Eventually this task was moved to the House of Commons Standing Committee on Health when then-Minister of Health Alan Rock presented the Standing Committee with *Proposals for legislation governing assisted human reproduction* (Health Canada 2001). In the months that followed, a number of interested "experts" (including Françoise Baylis) appeared before the Standing Committee.

In 2004 the *AHR Act* received Royal Assent, at which time work began on the development of regulations pursuant to the legislation. Public involvement activities for this rule-guided consultation included a number of topic-specific workshops with different constituencies. For example, medical fertility clinics and laboratories of assisted reproduction services were consulted on the licensing and regulation of controlled activities and the obligations of licensees regarding health reporting information. Before this, patients/consumers of assisted reproduction services were consulted on the development of regulations under the *AHR Act* with respect to: aggregate outcomes of AHR procedures; health reporting information; counseling; and information to be made available to the public by Assisted Human Reproduction Canada. Nothing came of these public consultations, however, ostensibly because of the pending constitutional challenge.

When the *AHR Act* was amended by the federal government in March 2012, in part in response to the SCC decision of December 2010 (according to which several sections of the *Act* were unconstitutional), there were no public consultations.

Communicative Action and Research Guidelines for Embryo (Stem Cell) Research

The mandate of the CIHR Working Group on Stem Cell Research was very modest compared with that of the Royal Commission. The Working Group was not expected to develop an ethical framework for stem cell research, but rather to work within

existing frameworks as found in the final report of the Royal Commission (1993) and in the 1st edition of the *TCPS* (MRC et al. 1998). This meant, for example, that the permissibility of *ex utero* human embryo research up to day 14 was not subject to debate and discussion. Within this limit the Working Group was to advise CIHR on the research use of human embryos (and other human tissues) to derive and study human pluripotent stem cells. As well, the Working Group's mandate did not include public consultation; this was undertaken at the initiative of (some) members of the Working Group.

Consistent with the goals and objectives of communicative action, and in an effort to simulate some form of dialogue, all comments received from the Canadian public were summarized and distributed to members of the Working Group for consideration. Some of these comments informed the Working Group's discussions and influenced the drafting of the final report. Other comments (especially bulk form letters that addressed issues beyond the limited mandate of the Working Group) had little impact. All comments from the public received a formal reply in aggregate in an Appendix to the Working Group's final report. Here there was an attempt to explain whether and how the public input had been included in the final policy recommendations. As appropriate, links were drawn between expressed concerns and measures taken by the Working Group to address those concerns in its final report.

There were, for example, concerns about the composition of the Working Group and about use of the web to solicit feedback from Canadians. With respect to the first concern, the Working Group was in the awkward position of having to generate an explanation for a decision into which it had no input. For good or ill, the Working Group defended its membership stressing the need for scientific expertise and noting that some members (presumably, the two philosophers and the sole lawyer) had no personal commitment to the pursuit of stem cell research. With regard to the second concern, about whether the consultation mechanism (posting a Discussion Paper on the CIHR website and inviting written comments) was an effective means of soliciting public input, the Working Group offered the following comment acknowledging the possibility of bias:

> The original mandate of the Working Group did not include a public consultation phase and it was initially anticipated that the Working Group would report back to the Governing Council of CIHR by June 2001. The consultation was done at the initiative of the Working Group and an extension of the reporting deadline was sought. The Working Group and CIHR also made sure that the document received wide media coverage to ensure that its existence became known to interested parties. The goal was never to do a full survey of Canadians' views on this topic – that would have required a different mandate, budget and time frame. Although the Group's survey of public opinion was limited and possibly biased, it did identify many issues that informed the final report. (CIHR WG 2002)

In this reply (as in others) there is evidence of a willingness to be challenged, a key feature of communicative action. Is there also evidence of a willingness to set aside preferences "for the sake of truth-seeking … [to identify] the best possible policy solution for the problem at issue?" (Montpetit 2003, 101). This is much less clear and arguably this is where the issue of membership bias in favour of the research community is most germane. It is not clear (indeed it is doubtful) that a

majority of the members of the Working Group were able or willing to adopt a true problem-solving orientation to policy design regarding stem cell research in Canada. The Working Group was advisory to CIHR, a federal granting Agency with a clear preference to fund at least some human pluripotent stem cell research (albeit within a clear ethical framework).

Strategic Consultation and Research Guidelines for Embryo (Stem Cell) Research

In October 2007 the CIHR SCOC initiated a four-month strategic public consultation on a discrete business issue of critical importance to the future of hES cell research in Canada (CIHR 2007b). This consultation is here described as strategic because, in our view, those conducting the consultation had a clear policy preference for which they were seeking input-oriented legitimacy; namely, to exempt certain hES cell lines from the requirement that they be available to other researchers on a cost-recovery basis. The goal of the consultation was not to generate policy options (as would be the case with consultations conducted in the mode of communicative action), but rather to persuade those who were consulted to support the preferred policy option. Below we explain the strategic nature of this public consultation.

At the time the CIHR SCOC consultation was initiated (October 2007), the *Updated Guidelines for Human Pluripotent Stem Cell Research* had, since 2005, been tri-Agency guidelines and not merely CIHR guidelines. As such, since 2005 the requirement that hES cell lines derived in Canada be (1) included in an hES cell registry and (2) available to other researchers on a cost-recovery basis applied to hES cell lines established through research funded by one or more of all three federal research granting Agencies or conducted in Agency funded institutions—not just hES cell lines established through the use of CIHR funds (as per the 2002 Guidelines). Vestigial wording in s. 6.0 from the 2002 Guidelines created confusion, however. The preferred policy option in 2007 was to amend this requirement so that only those hES cell lines established with funding from one or more of all three federal research granting Agencies would be available to other researchers on a cost-recovery basis, while hES cell lines established in Agency funded institutions, but without Agency funding, would be exempt from this requirement.

The online survey included the following statements followed by a simple request for agreement (i.e., endorsement of the preferred policy options):

> SCOC suggests that the registry include the following [hES cell] lines to be subdivided into two distinct lists:
>
> 1. lines established through research approved by SCOC and with funding from any of the Agencies (not just CIHR). These lines would be listed in the registry and made available by the researcher to other researchers on a cost-recovery basis. *Do you agree with this application of the registry?*

2. lines established through research approved by SCOC and carried out in an institution that receives Agency funding, but whose derivation was not directly funded by an Agency. These lines would be listed in the registry but there would be no requirement for the researchers to make the cell lines available to other researchers on a cost-recovery basis. *Do you agree with this application of the registry?* (CIHR 2007b)

The information provided to prospective survey participants in support of the first policy choice explained the need to expand the registry in the following terms:

> The planned incorporation of the Guidelines into the *Tri-Council Policy Statement* (TCPS) is an argument in favor of expanding the scope of the registry. Such incorporation would, *per force*, expand the registry's scope because compliance with the TCPS is required for all research conducted in institutions receiving funds from the Agencies. It is also felt that the registry would be less useful if it did not include all hES cell lines derived under the auspices of an institution receiving Agency funds. (CIHR 2007b)

The reference to "expanding the scope of the registry" was inaccurate, however, as was the suggestion that this would happen, *per force*, with the planned incorporation of the *Updated Guidelines for Human Pluripotent Stem Cell Research* into the *TCPS*. In point of fact, the first policy option was merely a statement of the *status quo* since 2005. As explained above, since then the *Updated Guidelines for Human Pluripotent Stem Cell Research* (as stipulated therein) already applied in their entirety to "all research involving human pluripotent stem cells that is funded by the Agencies, or is conducted under the auspices of an institution that receives any Agency funding" (CIHR 2005b, s. 7.0), specific references to CIHR notwithstanding. This is because "NSERC and SSHRC joined CIHR in agreeing to a Tri-Agency approach requiring adherence to the Guidelines as a condition for Agency funding of research. This will apply until the Guidelines are formally incorporated into the TCPS" (CIHR 2005b, s. 3.0). Further, the *Guidelines for Human Pluripotent Stem Cell Research: Policy Details* explained that:

> New or ongoing human stem cell research that is:
>
> 1. funded by the Agencies; or
> 2. conducted under the auspices of an institution that receives any Agency funding, whether on site or off site; or
> 3. conducted elsewhere with any source of funding, by faculty, staff or students from an institution that receives Agency funding, must be in conformity with the Guidelines. (CIHR 2005c)

It follows that *all* hES cell lines established with Agency funding or conducted under the auspices of an institution that received any Agency funding had to be included in the Canadian stem cell registry and be made available to other researchers on a cost-recovery basis. This fact suggests that the SCOC's strategic public consultation may also have been strategic in the pejorative sense, viz. "calculated to take advantage of" those consulted. To be clear, there was no need for the SCOC to recommend statement (i) as this was already required in the *Updated Guidelines for Human Pluripotent Stem Cell Research*. But if the SCOC consultation was only about statement (ii), it would not have been possible for the SCOC to present the recommendation to exempt certain hES cell lines from the requirement that they be "made available to other researchers, subject to reasonable cost-recovery charges"

(CIHR 2007a, s. 6.0) as a reasonable limit on an effort to otherwise increase the availability of Canadian hES cell on a cost-recovery basis— i.e., the impression created with statement (i). Indeed, a public consultation limited to statement (ii) would have made transparent the intention to limit (not expand) the availability of hES cell lines on a cost-recovery basis and this could have undermined public support.

The results of the strategic public consultation on expanding the scope of the hES cell registry were made public in June 2009, more than a year after the survey was conducted and the results were discussed by the SCOC (CIHR 2009). In response to the second question about hES cell lines at an institution that receives Agency funding, but whose derivation was not directly funded by an Agency, a majority of respondents (19) agreed that these hES cell lines need not be made available on a cost-recovery basis. A lower, but nonetheless relatively significant, number of respondents (12) disagreed with the proposed policy change, with "[s]everal respondents [noting] that the lines should be made available on a cost-recovery basis, regardless of the funding source" (CIHR 2009).

At the same time the survey results were made public, a national electronically accessible registry of hES cell lines was finally created. Initially, there were no hES cell lines listed in the registry despite the fact that at least four such lines had been derived in Canada and approved by the SCOC for research use. This was at odds with the *Updated Guidelines* according to which all hES cell lines established through research funded by one or more of the federal funding Agencies or conducted in Agency funded institutions were to be (i) included in an hES cell registry and (ii) available to other researchers on a cost-recovery basis, specific reference to CIHR notwithstanding. This was also in direct conflict with the clear reach-through provision in the *TCPS* and Agency-institution Memorandum of Understanding. Confusingly, CIHR initially characterized listing lines in the registry as a voluntary decision: "[i]nvestigators with lines derived under the auspices of an institution that receives Agency funding *will be asked if they wish to voluntarily list their cell lines*" (CIHR 2014b).[3] In June 2010, instructions on participation in the registry were amended clarifying that all hES cell lines derived under the auspices of an institution that received Agency funding was mandatory. In July 2010 four hES cell lines were listed in the registry. At May 2016 the total had not changed.[4]

Of note, CIHR explained the history of the *National registry of human embryonic stem cell lines* in such a way as to ignore the fact that in 2005 the *Updated Guidelines* were the remit of all three federal funding Agencies, not CIHR alone. In describing the National registry, CIHR stipulated in error that "prior to June 30, 2010, only human embryonic stem cell lines derived in the course of CIHR-funded projects were required to be listed in the registry" (CIHR 2014b).

[3] The text cited here appeared on the CIHR website when accessed in 2009, at which time it was properly cited in Baylis and Herder (2009b). It has since been amended.

[4] The website for the National registry of human embryonic stem cell lines was last updated on December 19, 2014. http://www.cihr-irsc.gc.ca/e/39580.html Accessed 29 May 2016.

Policy Design for Human Embryo Research in Canada: What Might the Future Hold?

As we look to the future, we note an important shift in the landscape of policy design for human embryo research in Canada–in the past 10 years, there has been no concerted effort to dialogue with Canadians about embryo research. Meanwhile, there is reason to think that the views of Canadians on the scope of acceptable hES cell research may have changed, or be in a state of flux. This is especially true given recent international debates on laws and policies governing germline genetic interventions with mitochondrial replacement technology and gene editing using CRISPR/Cas 9.

The science and practice of human embryo research is fast paced and there are frequent media reports of national and international political controversies, hoped-for-cures, and human tragedies. Against this ever changing, scientific, political, and social backdrop, it is possible that available information about the views of Canadians is outdated. This suggests the need for additional policy consultation, but there appears to be little appetite for this. Moreover, from the perspective of some, it would be preferable to access the contributions of interest groups and policy communities (i.e., tightly interconnected groups closed to a limited number of influential state actors (Montpetit 2004, 72)) as these might more easily contribute to cohesive public policy.

In Canada, the earliest of the knowledgeable, well-organized, well-connected, and well-funded policy communities with an interest in stem cell research was the Stem Cell Network (SCN). Since then a number of other such research communities have been created including the International Consortium of Stem Cell Networks in 2004, the Cancer Stem Cell Consortium in 2007, the Canadian Stem Cell Foundation in 2008, the Centre for Commercialization of Regenerative Medicine in 2011, and the CellCAN Regenerative Medicine and Cell Therapy Network in 2014.

The Stem Cell Network

The SCN is a non-profit organization created in April 2001 through the federal Network of Centres of Excellence program to serve as an interdisciplinary hub for researchers and clinicians across Canada engaged in the field of stem cell research. As currently described, the SCN mission is to be "a catalyst for Canadian research that translates stem cell research into new therapies, commercial products and public policy" (SCN 2015a). From the beginning, the SCN has had a clear interest in embryo policy in Canada.

The SCN research program began in earnest in January 2002 when individual projects received funding.[5] At this time, the House Standing Committee on Health

[5] This is a reference to the time at which individual research groups received monies through the SCN to begin their research.

was reporting back to the federal government on the draft legislation on assisted human reproduction, and the CIHR Governing Council was considering the final report of the *ad hoc* Working Group on Stem Cell Research. To this point in the policy process, individual members of the SCN may have had an impact on the legislation via presentations to the House Standing Committee on Health (see, for example, Baylis 2001) and on the guidelines *Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research* (CIHR 2002) via membership on the Working Group. The SCN as a discrete organization did not participate in policy design. However, in the two years between the adoption of *Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research* (CIHR 2002) and the passing of the *AHR Act* (2004), this changed. While the legislation was being debated in Parliament, SCN members testified before House and Senate committees and lobbied members of Parliament. Some SCN members spoke on behalf of the Network, others spoke on their own behalf. Some spoke in support of the legislation; some spoke against.

With the introduction of the *AHR Act* much of the overt advocacy activity temporarily quieted, but thereafter the SCN adopted a number of different strategies to enhance its influence.

First, in November 2005 the SCN created a multidisciplinary Policy Development Committee with a mandate "to consider issues of public policy relevant to stem cell research and with input from members and other stakeholders to develop draft position papers for approval by the SCN Board as representing the official views of the Stem Cell Network" (SCN 2006).[6] Since its inception the SCN's Policy Development Committee has published a total of 11 ethics and policy 'white papers' aimed at shaping public policy.[7]

The Committee's first position paper was on the "Use of human embryos for stem cell research". This paper which advocated the research use of fresh embryos aimed to legitimize (after the fact) research by an SCN researcher that resulted in the derivation of Canada's first hES cell lines. This paper also aimed to shore up the *Updated Guidelines for Human Pluripotent Stem Cell Research* which had been expressly amended in 2005 by the CIHR Governing Council (CIHR 2005a) "to recognize that fresh embryos (and not just frozen embryos) are also being used for stem cell research" (CIHR 2005b).[8]

In Canada, consistent with the *TCPS2*, only embryos "no longer required for reproductive purposes or other purposes permitted under the *Assisted Human Reproduction Act*" can be used for research. Prior to 2005, it was generally understood (consistent with practice in IVF clinics) that "embryos no longer required for reproductive purposes" included (1) poor quality embryos unsuitable for embryo transfer or freezing and (2) frozen embryos not intended for thawing and embryo transfer (see, Rivard and Hunter 2005, 135–136; Baylis and McInnes 2007, 64 and

[6] The initial co-Chairs were Janet Rossant, previously the Chair of the CIHR *ad hoc* Working Group, and Bartha Knoppers, previously a Commissioner with the Royal Commission.

[7] http://www.stemcellnetwork.ca/index.php/ethical-legal-and-social-issues/

[8] Whereas typically practice is made to conform to guidelines, in this instance guidelines were made to conform with practice. The 2002 Guidelines did not discuss the use of fresh versus frozen embryos for hES cell research. Once it became clear that researchers were using fresh embryos for hES cell research, the 2005 Guidelines were amended to legitimize this research. For a detailed discussion of this see Baylis and McInnes (2007), and McLeod and Baylis (2007).

66). This understanding changed with the 2005 *Updated Guidelines for Human Pluripotent Stem Cell Research* which allowed fresh embryos to be considered in excess of clinical need regardless of whether these embryos were suitable for transfer or freezing (CIHR 2005b). This policy change was made despite the fact that asking women infertility patients to donate their fresh embryos to hES cell research is: (1) contrary to the Canadian Medical Association (CMA) Code of Ethics and the physician's primary obligation to promote patient interests (Nisker and White 2005b); (2) contrary to women's reproductive interests, (Baylis and McInnes 2007; McLeod and Baylis 2007); (3) challenges the process of informed consent (Nelson et al. 2008); and (4) unnecessary—a majority of hES cell lines have been derived from frozen embryos "in excess of clinical need", and poor quality embryos that have reached the blastocyst stage are a robust source of normal hES cells (Lerou et al. 2008).

Second, in a further effort to influence "the regulatory landscape" for stem cell research, the SCN set about developing a policy framework that would advance the interests of the stem cell research community:

> To deliver its message to political leaders and to the public, the Network organized presentations on Parliament Hill, expert testimony to the Standing Committees of the House of Commons and the Senate, letters and briefing notes to every MP and senator and participated in extensive engagement with the media, including over 300 appearances by Network researchers in the national press, TV and radio.[9]

Third, SCN policy objectives were also pursued through research and academic publications in collaboration with those responsible for the oversight of stem cell research. Consider, for example, an early collaboration between members of the SCN and members of the CIHR SCOC who together published an article defending the use of fresh embryos in hES cell research (Cohen et al. 2008).[10] The CIHR SCOC is the national oversight committee mandated to: i) provide CIHR Governing Council with policy advice on ethical and scientific issues (including advice on the development, interpretation, and implementation of the rules governing stem cell research), and ii) to provide ethics review of stem cell funding applications (many of which would be submitted by SCN researchers). To avoid potential, apparent, and actual conflict of interest, CIHR SCOC members should not have been collaborating with SCN researchers on policy matters that directly impact research that is subject to SCOC review. While the SCN's website explicitly describes its strategic program examining the social, ethical, and legal implications of stem cell research as being "arms-length",[11] the above example of collaboration suggests otherwise, and speaks to the skill of the SCN in advancing its policy objectives.

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[9] http://www.stemcellnetwork.ca/index.php/evidence-based-policy-making/

[10] At the time this article was published (May 2008), three of the authors (Knoppers, Isasi, and Nagy) were SCN-funded researchers, Cohen and Dickens were former SCOC members, and Brandhorst, Leader, and Evans were current SCOC members. In our view, it is possible (likely) that the former SCOC members were current SCOC members at the time the original manuscript was prepared. In the body of the article the authors acknowledge that five of the authors "are current or former members of the SCOC" (Cohen et al. 2008, 417). In the acknowledgements, three of the authors "thank the Canadian Stem Cell Network for funding support" (Cohen et al. 2008, 420). Nowhere in the article is there a statement about conflict of interest.

[11] http://www.stemcellnetwork.ca/index.php/ethical-legal-and-social-issues/

Fourth the SCN has also been successful in collaborating with various health charities that are well-positioned to support SCN policy objectives. It is generally understood that in some domains, not-for-profit organizations such as health charities have been co-opted by private interests (Batt 2010). The pharmaceutical industry, for example, has been quite successful in utilizing health charities as a means to "inform" patient populations about drugs "of questionable benefit" (Angell 2004; Herxheimer 2003). In the realm of stem cell research, the risk of capture does not appear to be an issue—not because health charities interested in hES cell research have a unique immunity to capture, but rather because their interests appear to be broadly aligned with those who promote hES cell research, including the SCN. As at 2009, the SCN counted 43 health charities/not-for-profit organizations among its partners. In addition to joint investment in research, partners collaborate with the SCN "on education and public awareness initiatives in order to encourage public dialogue on the potential of stem cell research in the context of a realistic understanding of where we are today" (SCN 2009).

The official positions of individual charities/not-for-profit organizations on stem cell research have not been uniform. Nonetheless, to the extent that the SCN has been able to coordinate a common front between the research community and the health charities/not-for-profit sector, it has succeeded in creating an impression of enthusiastic public support for the research efforts of stem cell scientists and the efforts to create a more permissive research environment.

Fourth and finally, the SCN has been able to advance its policy interests through its research portfolio, which included a Strategic Program on Public Policy & Ethical, Legal & Social Issues. This program aimed to support research that "focused on projects … of interest to policymakers and to an ELSI [Ethical, Legal and Social Issues] core facility.…Guided by the SCN's Clinical Trials committee, the facility prioritizes *where the Network can have the most impact in easing the ethics/regulatory/policy pathways* and undertakes or co-ordinates work to address the hurdles" (emphasis added) (SCN 2008).[12]

In summary, the SCN has been able to effectively participate in public consultations on human embryo research through its Policy Development Committee, its diverse collaborations (with CIHR's SCOC and with various health charities/not-for-profit organizations), and its own research agenda. The future is uncertain, however. Federal funding for the SCN through the Networks of Centres of Excellence program has come to an end and it is looking for other funders. If it is successful in attracting research funds, interest in contributing to policy initiatives as opportunities arise will probably continue. If it is not successful in attracting additional research funds its policy influence may or may not wane. While individual researchers and research teams might be pursuing their research independently, it is easy to imagine that with 14+ years of research collaboration, past SCN members could

[12] This wording originally appeared in a description of the Stem Cell Network Strategic Program IV: Public Policy & Ethical, Legal & Social Issues published in 2008 at http://www.stemcellnetwork.ca/research.php. This was eliminated from the SCN website following the publication of Baylis and Herder (2009b). The text cited can be retrieved through www.archive.org by: (1) inserting http://www.stemcellnetwork.ca/ in Search box; (2) selecting the date May 26, 2008; and (3) following the 'Research' footer at the very bottom of the page.

effectively mobilize should there be future opportunities to inform/influence public policy on human embryo research in Canada.

Future Policy Design Consultations

For many and varied reasons, for the past 15 years, the SCN has been well positioned to influence future policy consultations on human embryo research in Canada. First, as a Network of Centres of Excellence in stem cell research, the SCN carried with it the traditional authority of science. Second, having world class researchers among its members was an additional source of power and authority, as was its leadership role in creating the International Consortium of Stem Cell Networks (ICSCN) (ICSCN 2005). The mandate of the ICSCN is to facilitate international cooperation and to pursue collaborative research in areas of mutual interest including "stem cells and public policy". Third, the SCN readily assumed an air of reasonableness owing to its efforts at internal self-regulation (i.e., SCN policy documents) and its acceptance of external oversight (e.g., research review by the CIHR SCOC). Fourth, as noted above, there were structures and partnerships in place to produce and promote highly cohesive policy positions on human embryo research. Fifth, there was the weight of the SCN's financial interest in human embryo research. The SCN's total budget from the Networks of Centres of Excellence program from 2001 to 2017 is $CAD 83.3 million (SCN 2015b). A portion of this research budget directly funded hES cell research and was also used to leverage additional research funds. Sixth, through its partnerships with industry and specific initiatives like the creation of Aggregate Therapeutics Inc., or more recent entities like Centre for Commercialization of Regenerative Medicine (CCRM 2015), the SCN's full embrace of commercialization was in keeping with the federal government's core science and technology policy objectives (Herder and Dyck Brian 2008; Government of Canada 2007).

For all of the above reasons, the SCN's participation in policy design commanded significant attention and constituted a considerable counterweight to the contributions of interested Canadians. The consequences of this power imbalance could be damaging to future public consultation efforts (and the legitimacy of any policy decisions that might flow from such efforts) in at least two ways. First, public consultations may be more apt to be undertaken by interested experts (not the government) for strategic purposes and may intentionally privilege participation by the medical and research communities over participation by interested "non-expert" Canadians. Second, insofar as future public consultations are primarily strategic in nature (and driven by the research community), these consultations may mask important differences between values that come to be identified as "Canadians values" and the actual values of average Canadians.

In either of these instances, input-oriented legitimacy would be seriously compromised. In the first instance, the information generated through the public consultation would come largely from a discrete "interested" constituency but be (mis) described as "public" input. In the second instance, the issue would not be biased participation so much as biased interpretation.

Conclusion

The public consultations that have contributed to the formulation of current embryo research policy in Canada (legislation and research guidelines) have not been free from controversy. But at least conflicting views and interests of Canadians have been relatively transparent which, in our view, is essential for informed and respectful debate, not to mention strengthening the input-oriented legitimacy of any resulting policy.

However, over the years, Canadians have been less and less involved in policy design for embryo research. One plausible reason for the decline in citizen engagement is the sheer cost of meaningful public consultation. This requires a significant investment (in both time and resources) in public education, data collection, and analysis. Another equally plausible reason for the decline is the belief among some civil servants and politicians that the time for public consultation has passed.

We are less convinced. As noted above, legitimacy in policy design depends, in large measure, on achieving an appropriate balance between output- and input-oriented legitimacy. What is "appropriate" will depend on: i) what policies are already in place; ii) what consultation efforts preceded the introduction of these policies (and, more precisely, whether relevant and diverse constituencies were consulted and heard); iii) what power dynamics currently exist between various interest groups and policy communities; and iv) the nature of the policy choice under consideration. In our view, the best way to ensure that no one particular set of interests dominates the agenda in this ever-shifting area of public policy is to regularly assess (and as needs be adjust) the balance between output- and input-oriented legitimacy.

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Competing Interests Françoise Baylis was a member of the Canadian Institutes of Health Research (CIHR) *ad hoc* Working Group on Stem Cell Research from November 2000 to December 2001 and a member of the CIHR Governing Council from December 2001 to December 2004. She was a Principal Investigator funded by the Stem Cell Network from January 2002 to December 2005. In 2006 she prepared an Expert Opinion for the federal government in *Attorney General of Québec v. Attorney General of Canada*. From 2006 to 2010 she was a member of the Board of Directors of Assisted Human Reproduction Canada. The views expressed herein are her own.

Appendices

Appendix 6.1: Royal Commission on New Reproductive Technologies, Proceed with Care

Consultations and communications

Input from Canadians

Public and Private Hearings: more than 550 Canadians took part in and presented briefs to public hearings across the country.

Submissions and Letters of Opinion: 500 written submissions and opinions up to September 1993.

Personal Experiences and Private Sessions: 500 individuals wrote to the Commission about their personal experiences or participated in private sessions held across the country.

Information Meetings: to consult organizations such as public health associations, women's groups, religious organizations, groups representing people with disabilities, the legal and medical professions, the research community, and the pharmaceutical industry.

Search Conference: three-day session involving 32 experts in fields such as health, law, bioethics, and religion, as well as representatives of people with disabilities.

Public Opinion Research: more than 15,000 surveyed; surveys explored awareness, values, and attitudes.

Toll-Free Telephone Lines: to facilitate participation in the Commission's consultations for people who might have found it difficult or inconvenient to participate through hearings or submissions; to provide access to information about the Commission and its work; more than 6000 calls received.

Informing Canadians

Research Reports Released: Commission released 14 research studies during its mandate.

Newsletter Published: 50,000 copies of semi-annual newsletter, Update, detailing our research and other activities, were distributed through mailing list and public events.

Distribution and Information: 250,000 pieces of information distributed during the life of the Commission, such as information kits, brochures on the public participation and research programs, newsletters, speeches; information for use by community newspapers, journals, and opinion and editorial page editors; and information distribution also by cable television and satellite networks.

Media Activities: more than 1,000 media interviews were given and more than 7,000 media articles appeared about the Commission and its work.

Appendix 6.2: Discussion Group on Embryo Research

Summary of recommendations

Recommendation 1

No research on human embryos should be allowed unless it is approved and overseen on an ongoing basis by a National Regulatory Body (NRB). Violations should be subject to criminal sanction.

Recommendation 2

Human embryo research should be allowed only:

1. after the exhaustion of useful inquiry using animal or other non-human models;
2. when demonstrably necessary for the improvement of the human condition;
3. when of the highest scientific quality as determined by rigorous peer review; and
4. when approved by the NRB.

This recommendation should be incorporated in the appropriate legislation.

Recommendation 3

In keeping with current internationally accepted norms, research involving developing human embryos, ex utero, should not be permitted later than 14 days after conception. This limit should be subject to modification should there be new and compelling ethical or scientific justification to do so. This recommendation should be incorporated into appropriate legislation.

Recommendation 4

Viable human embryos should only be used in research where a compelling case is made that non-viable embryos cannot be successfully employed. This recommendation should be incorporated into appropriate legislation.

Recommendation 5

For acceptable regulation of RHE, a National Regulatory Body must provide a process of oversight of the clinical practice of reproductive technologies, in cooperation with the appropriate provincial licensing bodies and professional organizations.

Recommendation 6

After the woman/couple has arrived at a settled intention not to use their embryos for gestation, they should be given the choice of donating them to another woman/couple for gestation or donating them for research or directing that they be discarded. This recommendation should be incorporated into appropriate legislation.

Recommendation 7

Any use of embryos for purposes other than consented to by the woman/couple should be subject to criminal sanction.

(continued)

Recommendation 8

Medical procedures related to infertility treatment should be undertaken with the sole objective of the medical well-being of the woman undergoing the procedures and the resulting offspring. Medical management should be directed toward minimizing risk and maximizing the likelihood of a successful pregnancy. Procedures must not be altered in any way that compromises the medical interests of the woman and the offspring, even if doing so would make ova or embryos available for research. This recommendation should be incorporated into appropriate legislation.

Recommendation 9

While approved clinical procedures exist which involve manipulation of the embryos, appropriate mechanism for their approval and monitoring should lie within the clinical domain.

This recommendation should be incorporated into appropriate legislation.

Recommendation 10

Fertilization of human ova for research is prohibited unless the National Regulatory Body considers the research proposal to contain an exceptional circumstance in which anticipated benefits to society or future offspring require that the experiment occur. Such knowledge would have to be unattainable by other means. Violations should be subject to criminal sanction.

Recommendation 11

All research or experimentation on a human embryo (including but not restricted to human cloning, chimeras, production of interspecies embryos and transgenic human embryos) without the explicit approval of the National Regulatory Body should be prohibited. Failure to secure such explicit approval should constitute a criminal offense.

Recommendation 12

In the absence of a National Regulatory Body vested with the powers listed in Recommendation 19, fertilization of human ova for research and research into human cloning, chimeras, production of interspecies embryos and transgenic human embryos should be banned without exception.

Recommendation 13

PGD should only be offered in the context of structured, clinical trials approved and monitored by the National Regulatory Body.

Recommendation 14

Even if proven to be safe and effective, PGD should only be available to diagnose the most serious of genetic conditions as established on a list by a National Regulatory Body, because of its potential social and health impacts.

Recommendation 15

Commercialization of gametes and embryos for research should be prohibited both within Canada and in the context of importation and exportation. Violations of this recommendation should be subject to criminal sanction.

(continued)

Recommendation 16

Payment for gametes or embryos shall not exceed the out-of-pocket expenses for the donors and the costs of handling, storing, transporting and transferring the gametes and embryos. Violations of this recommendation should be subject to criminal sanction.

Recommendation 17

Reduction in the price of IVF or other medical services should never be exchanged for gametes or embryos for use in research. This recommendation should be incorporated into appropriate legislation.

Recommendation 18

A multi-perspectival National Regulatory Body should be created by Parliament through legislation without delay. This body should have jurisdiction over all aspects of reproductive technology. This legislation should also specify which conduct should be subject to criminal sanctions.

Recommendation 19

The National Body created through Recommendation 18 should include but not be limited to the following powers with specific reference to RHE:

1. setting of technical standards of investigation, clinical practice, and education within an ethical framework;
2. ongoing exploration of emerging ethical issues in RHE;
3. approval of research protocols and monitoring of approved investigation;
4. accreditation and supervision of facilities and licensing of practitioners and researchers using human gametes or embryos, in cooperation with the appropriate provincial and national organizations;
5. defining violations and breaches of conduct, and the enforcement of sanctions;
6. development of a strategy for information management related to such priorities as registries, research outcomes and clinical practice guidelines;
7. undertaking other functions as detailed in recommendations in this report.

Recommendation 20

The mandate of the NRB should allow for delegation of powers (other than whose falling within criminal jurisdiction), and development of partnerships with the provinces as well as regional and professional bodies.

Appendix 6.3: Assisted Human Reproduction Act

Prohibited activities

Prohibited procedures

5. (1) No person shall knowingly

(a) create a human clone by using any technique, or transplant a human clone into a human being or into any non-human life form or artificial device;

(b) create an *in vitro* embryo for any purpose other than creating a human being or improving or providing instruction in assisted reproduction procedures;

(c) for the purpose of creating a human being, create an embryo from a cell or part of a cell taken from an embryo or foetus or transplant an embryo so created into a human being;

(d) maintain an embryo outside the body of a female person after the fourteenth day of its development following fertilization or creation, excluding any time during which its development has been suspended;

(e) for the purpose of creating a human being, perform any procedure or provide, prescribe or administer any thing that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an *in vitro* embryo, except to prevent, diagnose or treat a sex-linked disorder or disease;

(f) alter the genome of a cell of a human being or *in vitro* embryo such that the alteration is capable of being transmitted to descendants;

(g) transplant a sperm, ovum, embryo or foetus of a non-human life form into a human being;

(h) for the purpose of creating a human being, make use of any human reproductive material or an *in vitro* embryo that is or was transplanted into a non-human life form;

(i) create a chimera, or transplant a chimera into either a human being or a non-human life form; or

(j) create a hybrid for the purpose of reproduction, or transplant a hybrid into either a human being or a non-human life form.

Offers

(2) No person shall offer to do, or advertise the doing of, anything prohibited by this section.

Payment for prohibited act

(3) No person shall pay or offer to pay consideration to any person for doing anything prohibited by this section.

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