

Stem Cell Research Ethics: Consensus Statement on Emerging Issues

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Abstract

This article is a consensus statement by an international interdisciplinary group of academic experts and Canadian policy-makers on emerging ethical, legal, and social issues in human embryonic stem cell (hESC) research in Canada. The process of reaching consensus included consultations with key stakeholders in hESC research (regulators, stem cell researchers, and research ethics experts), preparation and distribution of background papers, and an international workshop held in Montreal in February 2007 to discuss the papers and debate recommendations. The recommendations provided in the consensus statement focus on issues of immediate relevance to Canadian policy-makers, including informed consent to hESC research, the use of fresh embryos in research, management of conflicts of interest, and the relevance of public opinion research to policy-making.

Résumé

Le présent article est une déclaration de consensus émise par un groupe interdisciplinaire international de spécialistes universitaires et de décideurs canadiens au sujet des nouvelles questions éthiques, juridiques et sociales dans le domaine de la recherche sur les cellules souches embryonnaires humaines (CSEH) au Canada. Dans le cadre du processus visant l'atteinte d'un consensus, nous avons mené des consultations auprès d'intervenants clés du domaine de la recherche sur les CSEH (responsables de la réglementation, chercheurs s'intéressant aux cellules souches et spécialistes du domaine de l'éthique de la recherche), nous avons rédigé et distribué des documents d'information, et nous avons tenu un atelier international à Montréal en février 2007 pour discuter de ces documents et débattre de leurs recommandations. Les recommandations faisant partie de la déclaration de consensus sont axées sur des questions intéressant directement les décideurs canadiens, y compris le consentement éclairé en matière de recherche sur les CSEH, l'utilisation d'embryons frais à des fins de recherche, la prise en charge des conflits d'intérêt et la pertinence de la recherche sur l'opinion publique en ce qui a trait à l'élaboration des politiques.

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INTRODUCTION

Stem cell research continues to generate social controversy. Although this controversy seems inextricably linked to concerns about the moral status of the embryo,^{1,2} other issues such as concern for the welfare of gamete and embryo donors have emerged in policy debates around the world.^{3–6}

In Canada, the scope of permissibility of hESC research is now largely defined by the Assisted Human Reproduction

Act.⁷ However, a variety of ethical and policy issues relevant to hESC research have gained traction in Canada, such as the concern about the use of fresh (vs. frozen) embryos for research,^{8,9} the informed consent process,^{10,11} and the constitution of the AHR Agency, the body responsible for administering the provisions of the AHR Act.^{12,13}

The process leading to this consensus statement began with the identification of issues through a national, systematic consultation with key stakeholders, including regulators, researchers, and research ethics experts.¹⁴ This resulted in the production of five background papers on the identified issues: informed consent,¹⁵ conflicts of interest,¹⁶ public perceptions,¹⁷ clinical trial registries,¹⁸ and research governance.¹⁹ The papers were circulated to an international interdisciplinary group of experts and Canadian policy-makers who then met in Montreal on February 21 and 22, 2007, to discuss the papers and debate recommendations. The Montreal workshop included policy-makers, members of relevant research ethics boards, scientists, clinicians, and an interdisciplinary group of experts on stem cell research ethics issues.

The recommendations provided in this consensus statement focus on issues of immediate relevance to Canadian policy-makers. Indeed, the selection of the topics, made in early 2006, proved quite prescient. Several of the issues, such as the informed consent process for donation of gametes and embryos to hESC research and the avoidance of conflicts of interest in the constitution of relevant regulatory bodies, are currently centre-stage in policy debates in Canada and other jurisdictions.^{13,20–25} For example, regulations relating to the informed consent provisions under section 8 of the AHR Act were recently released,²⁶ and several national and international groups have issued guidelines on a variety of relevant research ethics issues.^{27–29}

It is important to consider some of the points made in the workshop discussions before the resulting recommendations are presented. Some concern was expressed about the tendency (in academic and policy debates) to render hESC research ethics issues exceptional and thus requiring the application of special rules. Participants questioned whether good evidence exists to support such special treatment. It was also suggested that the moral status debate and controversy surrounding hESC research might be overshadowing discussion of the ethical issues relevant to other areas of human stem cell research, including research using human stem cells derived from umbilical cord blood.

Participants noted the variance in the ethical concerns that dominate the policy debate in jurisdictions around the world as well as in Canada. For example, many of the international commentators were surprised by the degree to which the use of fresh embryos was an issue in Canada; in

ABBREVIATIONS

AHR	Assisted Human Reproduction
CIRM	California Institute of Regenerative Medicine
hESC	human embryonic stem cell
HFEA	Human Fertilisation and Embryology Authority
IVF	in vitro fertilization

other countries the issue is largely absent. Although the reasons for this are unclear, it raises the issue of policy interoperability and its possible impact on international collaborative research activities. Frameworks to address challenges in the context of international collaborative research are needed.³⁰

As stated previously, the focus of this consensus statement is on issues of immediate relevance to Canadian policy-makers, specifically issues of consent, conflicts of interest, and public opinion.

RECOMMENDATIONS

Consent Issues

Outlining a process of free and informed consent for hESC research was raised by the creation of Canada's first hESC line³¹ and is one of the pressing ethical issues facing Canadian policy-makers. It is highlighted in the AHR Act (s.8) and is the subject of the first batch of regulations made pursuant to the Act.²⁶ The informed consent process, the role of clinicians involved in treating infertile patients in the consent process, and the use of fresh embryos for research have also attracted a good deal of scholarly and media attention.^{9–11,32–34}

The involvement of independent clinicians in the consent process

Existing policies stipulate that the clinician providing care for an infertile patient should not be involved in the process of obtaining consent for donation of embryos to hESC research.^{31,35} This policy reflects concern over the possibility that the clinician may unduly influence the donor's choices. However, the duty of informed consent and the fiduciary obligations clinicians owe their patients are the usual safeguards against this concern. Moreover, existing consent rules appropriately require clinicians to be independent from the research protocol, thus reducing the conflict of interest concerns. Clinicians providing treatment are responsible for the consent process in other clinical research situations in which the risks of donor dependence and conflicts of interest are arguably more significant. Indeed, although international policies vary regarding the appropriate person to obtain consent for donation of embryos to research, the clinician providing treatment is not explicitly removed from the process in most jurisdictions.³² In addition, in Canada, as in other countries, the clinician is legally and morally responsible for clinical care.

Recommendation Given existing consent law, it is possible that the clinician providing treatment for an infertile patient bears the legal obligation to obtain informed consent for the donation of embryos for use in research. As a result, the clinician should have a role

in the consent process and arguably should be the individual to inform the patient qua potential donor about the research, answer any questions the patient may have, and obtain consent if the patient chooses to participate.

The use of fresh versus frozen embryos for research

Some have expressed the view that a moratorium should be placed on the donation and use of fresh embryos for research to protect the best interests of women undergoing IVF treatment.^{5,8,9} The fear is that donation of fresh embryos may decrease the chances of future pregnancy and increase the risk of harm from additional IVF cycles. However, existing policies permit the use for research of surplus fresh embryos originally created for reproductive purposes.^{27,35} Favoured policy options ought to respect the donor's freedom to make autonomous decisions regarding available reproductive choices so long as all material information necessary to make the decision has been provided. This approach accords with the Western traditions of autonomy and informed consent in health decision making. Policy-makers should avoid paternalistic assumptions about what is in the best interest of donors, unless there is evidence to support such assumptions.

Recommendation The use of fresh embryos for research purposes is ethically acceptable so long as an appropriate informed consent process is in place. There are two separate decisions needed in this context. The first decision—whether or not to cryopreserve embryos—should be made independently of the second decision—whether or not to donate embryos to research. Disclosure to women/couples who are considering donating fresh embryos to research must include an explanation that a decision not to cryopreserve embryos might reduce the chances of future pregnancy and will increase the chance that a woman will need to undergo another full IVF treatment cycle, with all of the risks inherent in that process.

Recommendation There is a need for empirical research on patients' perceptions of the informed consent process. Recommendations about what is ethically appropriate or what reflects "best practice" should, as far as possible, be evidence-based. We need to know what patients/potential donors would like to know before agreeing to participate in stem cell research, and with whom they are most comfortable discussing the risks involved in participating in research.

Conflicts of Interest

Conflicts of interest have long been a significant issue in the research environment.³⁶ As the stem cell research environment becomes ever more commercialized,¹⁶ the potential for conflicts seems likely to increase, particularly given the current trend for public funding agencies to encourage close ties with industry.¹⁶ Of course, conflicts of interest are more than just financial and can result from the implementation of legitimate social and innovation policy goals (e.g., policies promoting public interest in affordable therapies versus commercialization goals),^{37,38} and the secondary interests of researchers, research ethics board members, and institutional decision-makers.^{16,39}

Management of conflicts of interest

Concerns about conflicts of interest have attracted significant attention in the context of Canadian stem cell research policy.¹⁶ These concerns have resulted in rules that limit the types of individuals who can serve on the national research ethics board⁴⁰ and with the AHR Agency.^{7,12} For example, the AHR Act precludes persons licensed to carry out activities under the Act (including hESC research) or potential licensees from serving on the Board of Directors of the AHR Agency (s. 26(8)),⁷ and researchers affiliated with the Stem Cell Network and their collaborators cannot serve as members of the Stem Cell Oversight Committee.⁴⁰ The practical effect of these rules is the exclusion of many of the most qualified experts from overseeing or monitoring a developing area of knowledge in which specific expertise of the scientific and ethical issues raised would appear to be essential.

Such concerns over conflicts of interest in the membership of regulatory bodies have been raised in other jurisdictions and have (among other reasons) provided the basis for a lawsuit filed against the CIRM, the agency that funds and monitors stem cell research in California.^{20,41} However, most rules allow for relevant expertise on stem cell research monitoring boards subject to strict conflict of interest management policies. For example, CIRM rules ensure that although experts and investigators can be appointed to relevant regulatory and oversight boards, they are precluded from applying for or receiving CIRM research funds and from acting as principal investigators on CIRM-funded projects.^{42,43} The California rules also give CIRM management the discretion to allow persons with significant conflicts of interest to serve on various committees when the need for special expertise outweighs the possible bias posed by the conflict of interest.⁴³ Similarly, UK legislation allows infertility clinicians and scientists involved in hESC research to serve as members of the HFEA, the body responsible for overseeing embryo research.⁴⁴ However, to ensure independence and objectivity, the chair and the deputy chair and

at least half the members cannot be clinicians or scientists who conduct human embryo research or provide infertility treatment. A recently published study of IVF patients' perceptions of the UK's embryo research regulator, the HFEA, also found that there is "overwhelming support for doctors to be the most important members of the Authority, followed by researchers working in the area."⁴⁵

Recommendation Conflicts of interest that arise in the context of stem cell research are not qualitatively different from those that arise in other areas of health research involving significant clinical elements and therefore do not require special rules.

Recommendation When addressing conflict of interest issues, there is a need to balance the requirement for expertise against actual and perceived conflicts. It is essential to have relevant scientific, ethical, and other expertise in relevant regulatory bodies, and rules that permit the exercise of discretion for assessing the degree of conflict versus the need for specific expertise should be established. This seems particularly important in a jurisdiction such as Canada that has a limited number of experts. Excluding experts with vested stakes in outcomes is one way of managing conflict of interest ethically. Other ways of managing conflicts (such as disclosure and transparent decision making) may be equally acceptable.

Public Perceptions

Both those who support and those who oppose stem cell research frequently employ public opinion data to justify their respective positions.^{2,46} For example, such data have been used in the Canadian parliamentary debates and other policy discussions on the AHR Act to support a ban on somatic cell nuclear transfer² and in the lobbying efforts of interest groups and advocacy groups in many jurisdictions.^{2,17,46,47} Given the controversial nature of the research, this approach is not surprising. Citing public support for a contested policy position will undoubtedly lend the position with a measure of legitimacy or apparent democratic approval. Public opinion scholars emphasize the need for careful examination of methodologies used and, in particular, how questions are framed to gauge the reliability and validity of data before these are considered in policy contexts.^{46,48,49} In addition, the role of public opinion in policy debates must be considered, as few would suggest that it should be the sole determinative consideration.

Recommendation

Given the polarized nature of the debate, there is a need to appraise the meaning and significance of public opinion data critically, especially if it is to be used as a

justification for policy action. However, understanding how members of the public view and assess stem cell research remains essential. There is, therefore, a need for the development of innovative public engagement strategies and research methodologies.

Many research issues, such as the rationale for creating a registry for clinical trials of stem cell therapies, have not been addressed in this consensus statement.¹⁸ However, many of the recommendations made here could be of immediate relevance to Canadian policy-makers. If adopted, they would allow clinicians independent of the research to obtain consent and to clarify when the use of fresh embryos is appropriate. The Standing Committee of Health recently called for policies addressing the latter.⁵⁰ In addition, the conflicts of interest recommendations could have direct impact on the composition of oversight entities, such as the AHR Agency and the Stem Cell Oversight Committee. Lastly, an assessment of the value of public opinion research in policy-making could help inform and focus its use in future policy debates, including the review of the AHR Act by Parliament in 2009.

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