

Eligibility of Cryopreserved Human Embryos for Stem Cell Research in Canada
The Importance of Empirical Research in Bioethics: The Case of Human Embryo Stem Cell Research

To the Editor:

In the October issue of the *Journal of Obstetrics and Gynaecology Canada*, an ethics research paper on the Eligibility of Cryopreserved Human Embryos for Stem Cell Research in Canada¹ and an accompanying editorial² may have led to some unjustified concern about the ethical use of human embryos in scientific research in general and stem cell research in particular.

The paper, authored by Dalhousie University's Françoise Baylis and Natalie Ram, found that only one of 14 in vitro fertilization (IVF) clinics surveyed had followed the full consent process required by Canadian Institutes of Health (CIHR) guidelines for the use of embryos for stem cell research. An accompanying editorial by McGill University law and ethics professor Margaret Somerville essentially accused researchers of a "breach of trust" by assuming that they had proceeded with research without appropriate consent.

We fail to understand how this conclusion could have been reached. As far as we know, only three IVF clinics in Canada are involved with hESC derivation, and it is unclear whether any of these participated in the Baylis-Ram study. Moreover, only scientific projects whose research consent

forms have been reviewed by the researchers' local ethics board and the Stem Cell Oversight Committee of CIHR can receive funding from granting agencies. For our part, the Stem Cell Network will only fund hESC derivation studies that have met these strict regulatory standards. Therefore, the suggestion that scientists have violated the public trust is completely unwarranted.

The Stem Cell Network, which funded the Baylis-Ram study, absolutely concurs with the importance of conducting research under the highest ethical standards and with the appropriate ethical consents in place. Ethics research is important work and, indeed, there should be more research nationally and internationally to fully understand the way that scientific study is conducted. However, as in all areas of research, it is important to avoid overly generalized conclusions.

Judy Birdsell, Chair,
Board of Directors, Stem Cell Network

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1. Baylis F, Ram N. Eligibility of cryopreserved human embryos for stem cell research in Canada. *J Obstet Gynaecol Can* 2005;27(10):949-55.
2. Somerville MA. The importance of empirical research in bioethics: the case of human embryo stem cell research. *J Obstet Gynaecol Can* 2005;27(10):929-30.

In Response

To the Editor:

Judy Birdsell conflates our research paper¹ and the editorial written by Margaret Somerville.² We accept responsibility only for our arguments, evidence, and conclusions. Further, we take exception to some comments and claims made in Ms Birdsell's letter.

On behalf of the Board of Directors of the Stem Cell Network, Ms Birdsell writes "[a]s far as we know, only three IVF clinics in Canada are involved with hESC derivation, and it is unclear whether any of these participated in the Baylis-Ram study." As confidentiality was promised to the survey respondents, we cannot disclose whether any of the

three clinics known to the Stem Cell Network participated in our study. Perhaps all of the IVF clinics known to the Stem Cell Network have adequate consent forms but did not participate in our study. Then again, perhaps all of these clinics participated in our study and, therefore, at least two do not have adequate consent forms.

To our knowledge, the Stem Cell Network has funded three research teams to derive hESC lines. It is possible that one or more of these research teams receives embryos from more than one IVF clinic, in which case there may be more than three IVF clinics involved in hESC derivation research. It is also possible that there are Canadian IVF clinics involved in hESC derivation research that are not known to the Stem Cell Network. A third possibility is that

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there are stem cell researchers involved in hESC derivation research who are not using materials from the three clinics known to the Stem Cell Network. That said, it is important to note that, in our paper (co-funded by Associated Medical Services), our conclusion is limited to the following claim “we have identified only one Canadian IVF clinic with cryopreserved embryos unequivocally eligible for stem cell research.” This is hardly an “overly generalized conclusion.”

Ms Birdsell further asserts that “[f]or our part, the Stem Cell Network will only fund hESC derivation studies that have met these strict regulatory standards [review by the researchers’ local ethics board and the Stem Cell Oversight Committee of CIHR].” The ethics review processes referred to by Ms Birdsell, however, are neither “strict” nor “regulatory standards.” First, much has been written in the past few years on the woeful inadequacy of the current oversight mechanisms for the review of research involving humans. Second, the consent regulations for the *Assisted Human Reproduction Act* are not yet in place.

In our view, Ms Birdsell’s letter does nothing to undermine our conclusion that only one in 14 of the IVF clinics participating in our study was compliant with the CIHR guidelines. As such, there is no basis for her confident opening remark that “concern about the ethical use of human embryos in scientific research in general and stem cell research in particular” is unjustified.

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In Response

To the Editor:

There are two problems with Birdsell’s claims: first, she misinterprets what I said, and second, she argues that my conclusions¹ as to what Baylis and Ram’s study² showed are not correct.

Birdsell writes: “Margaret Somerville essentially accused researchers of a ‘breach of trust’ by assuming that they had proceeded with research without appropriate consent.” But as Baylis and Ram’s findings show, that was not an assumption on my part; some of them had indeed proceeded without appropriate consent, assuming that the consent forms Baylis and Ram reviewed were used in practice and were not just a theoretical exercise. So, leaving aside human embryo stem cell research for the moment, those carrying out research involving human embryos, which did not comply with the consent requirements, have breached that trust.

Speaking specifically about human embryo stem cell research, Birdsell continues: “We fail to understand how this conclusion [as to a breach of public trust] could have been reached. As far as we know, only three IVF clinics in Canada are involved with hESC derivation, and it is unclear whether any of these participated in the Baylis-Ram study. . . . Therefore, the suggestion that scientists *have violated the public trust* [in carrying out human embryo stem cell research] is completely unwarranted” (emphasis added).

What I actually said was that Baylis and Ram’s findings “show that in one of the most publicly debated, extremely controversial, painstakingly regulated areas of research in Canada ever, that of human embryo stem cell research, institutions *may not be complying* with the informed consent requirements governing such research” (emphasis added). That means some institutions and scientists carrying out such research *might have* violated public trust. That is not the same as saying “that [these] scientists *have* violated the public trust” as Birdsell claims I said.

In order to judge the validity of Birdsell’s claim as to the unwarrantedness of my suggestion about a possible breach of public trust in relation to human embryo stem cell research, let’s get straight the facts on which my conclusion in that regard is based. Birdsell’s description of Baylis and Ram’s findings that embryo stem cell research had proceeded without appropriate consent is incomplete in ways that matter with respect to whether my suggestion is “reasonably based” as required to justify it. The additions necessary to complete Birdsell’s description are in square brackets. In Baylis and Ram’s study “[all eligible IVF clinics in Canada were approached, 10 clinics did not respond to the survey and] only one of 14 in vitro fertilization (IVF) clinics [which responded among the 24] surveyed had followed the full consent process required by Canadian Institutes of Health (CIHR) guidelines for the use of embryos for stem

cell research.” Birdsell herself says that “[as] far as we know, only three IVF clinics in Canada are involved with hESC derivation, and it is unclear whether any of these participated in [*sic*: responded to] the Baylis-Ram study” [24 clinics participated, 14 responded]. Consequently, she says, “[w]e fail to understand how . . . [Somerville’s] conclusion [that there was a breach of public trust] could have been reached.” Note again that I did not say there was a breach of public trust in relation to human embryo stem cell research, but that there may have been such a breach. Is that, as Birdsell claims, a “completely unwarranted suggestion”?

Is it unreasonable—that is, unwarranted—to suggest that at least one of these three clinics *might have been* among the 13 who responded but showed non-compliance? Or, if all of them were among those not responding, to suggest that this group may not have been any more compliant with the consent requirements for embryo stem cell research than those that responded to the survey? And because that might be the case, is it unreasonable to say, as I said in my editorial,

that Baylis and Ram’s “findings should sound a serious warning for everyone connected with research, not least because what is involved (if such breaches are occurring and, as Baylis and Ram show, some certainly are in relation to consent to human embryo research, whether or not that is stem cell research) is not simply a matter of breaches of legal and ethical requirements in individual cases, but also a breach of public trust”?

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The Relative Value of Evidence

To the Editor:

After many years’ experience as a non-clinician academic coordinating clinical trials, I have recently become Director of Research in the Department of Obstetrics and Gynaecology at the University of Calgary. As director, I am involved in all department activities, including rounds.

Without question, the mortality and morbidity (M and M) rounds hold my attention more than any of the others. Every couple of months, cases are presented at the M and M rounds in which there has been an adverse event or bad outcome for the patient in a gynaecologic case or for mother or baby in an obstetric case. Following the presentations, there is very open and frank discussion among faculty members about what could have been done differently, the literature on the clinical problem, and others’ experiences of similar situations.

For someone who is not involved in clinical care, and whose professional life is spent in producing evidence to guide or support clinical practice, these rounds are a revelation. Watching clinicians describe adverse events affecting patients in their care is compelling and persuasive. Facial expression, posture, and tone of voice offer a strength of evidence I could never match in any paper published in a

peer-reviewed journal, no matter how well researched or written it might be.

As researchers, we tend to dismiss a single case report as being anecdotal evidence and thus as being of little or no value. However, since joining this department, I have needed to reassess my attitudes. If the results of clinical research support a favoured (and safe) course of action, then the evidence will be seen as guiding practice. If the results challenge a favoured course of action, then the implementation of evidence will take far more effort.

In the past, researchers have always regarded the pursuit of truth as paramount and the implementation of research as someone else’s responsibility. If we believe in the truth of our research findings and the importance of adopting them into clinical practice, we should learn from our clinical colleagues, step out from our sheltered offices, and present our findings widely, personally, and “*con brio*.”

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