

# Research ethics council faces dissolution

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Canada has long been viewed as somewhat of a desert with regard to oversight of research ethics boards, largely because it lacks any manner of accrediting or auditing watchdog.

It may now be a wasteland. The body involved in board review, the National Council on Ethics in Human Research (NCEHR), which largely operated in an educational mode, has had its funding yanked by Health Canada and the Canadian Institutes of Health Research.

It had once been hoped that NCEHR could be transformed into a national accrediting and oversight body for research ethics boards. But with the funding cut, some research ethicists fear that efforts to establish such an agency have been scuttled.

The lack of oversight is apparent in the whispered concerns expressed by Canadian research ethics experts, says Melody Lin, director of international activities and deputy director of the United States Office of Human Research Protections.

"I have been in every metropolitan area in Canada other than Halifax, from Victoria to Montréal," Lin says. "I've been all over in Canada and how many times has somebody whispered to me, 'Melody, why don't you come to Canada and do some inspections? You have the right to come to Canada to do some inspections. If you come and you find something, that will wake up everybody, because we don't do any inspections'."

The Office of Human Research Protections, a division of the US Department of Health and Human Services, has the authority to inspect ethics boards, or what are known south of the border as institutional review boards. Like the United Kingdom's National Research Ethics Service, which audits and accredits all research ethics committees within the National Health Service, it has the power to suspend a research ethics board or committee if its practices are unsafe or if it's not following research regulations.

Canada, by contrast, has only the NCEHR, which until Mar. 31 has for 20 years offered site visits to research ethics

boards. With a budget of about \$900 000, supported by in-kind contributions from the Royal College of Physicians and Surgeons of Canada, the council's staff of three coordinated a national network of volunteers who annually conducted an average of 6 to 12 on-site quality assurance evaluations at research ethics boards across the country.

One such panel was in the midst of conducting a review in Winnipeg, Manitoba, when word came down that funding had been axed. Later that week, Deborah Poff, the council's president and the president of Brandon University in Manitoba emailed colleagues that "effective immediately, NCEHR will be ceasing its educational activities on research ethics, research integrity and the promotion of voluntary peer-reviewed accreditation."

"I was kind of thunderstruck," says Michael McDonald, a chair of applied ethics at the University of British Columbia.

It was "a large loss to Canada in terms of how we do human subjects research," concurs Dr. Ray Saginur, a research ethics expert at the University of Ottawa in Ontario.

Although NCEHR panels did not report their findings to government and had no authority to mandate quality assurance reviews in cases where a research ethics board had problems, it was still the "principle organization to promote participant safety in Canada," says Heather Sampson, an ethicist at Toronto East General Hospital in Ontario and an NCEHR board member.

Research ethics board members often got their training at council workshops, and in some cases site visitors guided research ethics board functions. "It did happen sometimes that an institution would be at a point where they were completely dysfunctional," recalls Pierre Deschamps, an adjunct professor of law at McGill University in Montréal, Quebec and chair of NCEHR's site review committee for six years. In such cases, "we pitched in our own expertise."

Ken Davey, distinguished research professor emeritus in the department of biology at York University in Toronto, says panelists often found ethics boards weren't complying with



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Proponents argue that protection of human research subjects would be improved if Canada had a national body to accredit and audit research ethics boards.

research rules, either due to "ignorance or thoughtlessness."

Discontinuation of funding for NCEHR may also have kiboshed efforts to establish a national accrediting body for boards, as recommended by the Experts Committee for Human Research Participant Protection in Canada in 2008. It had been believed that the NCEHR would be chosen for that responsibility.

Lin says international counterparts like the US Office of Human Research Protections will miss NCEHR's presence. The pair had partnered in 2003 to form an organization called Forum for Institutional Review Boards (IRBs) / Research Ethics Boards (REBs) in Canada and the US. Their annual meeting, scheduled this year for Montréal in June, has now been cancelled.

Instead of discussing research ethics conundrums with their cross-border colleagues, Canadian research ethics experts may be fundraising. Poff says the council has incorporated as a non-profit organization and will be seeking donations to remain operational. — Miriam Shuchman MD, Toronto, Ont.

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