RESEARCH ETHICS

New Rules on Human Subjects Could End Debate in Canada

OTTAWA—After 4 years, three-dozen drafts, and $500,000, Canadian researchers are about to get a new code of conduct for research involving human subjects.

The new guidelines, a copy of which has been obtained by *Science*, will be issued later this month by Canada's three government research funding agencies—the Medical Research Council (MRC), Natural Sciences and Engineering Research Council, and Social Sciences and Humanities Research Council (SSHRC). The 4-year exercise revealed deep divisions within the scientific community over the best way to ensure ethical conduct, with biomedical researchers generally pushing for strict guidelines and social scientists arguing for a more flexible standard. The 84-page document represents a delicate compromise on issues ranging from the use of deception in social science research to definitions of what constitutes minimal risk for research subjects. Government and council officials have declined comment until the formal release of the new policy on 15 June.

The tricouncil ethics exercise, unpopular with most academics, was conceived to preempt the government from moving ahead with legislation on aspects of research involving humans. It followed a 1994 report by the Royal Commission on New Reproductive Technologies that recommended legislation to govern scientific activities in this highly charged field, as well as a study that found enormous variance in the workings of the institutional Research Ethics Boards (REBs) that monitor human experimentation.

For the most part, the guidelines lay out procedures that universities should follow for approving and monitoring such research. But they do include a few absolute prohibitions. For example, they would bar any form of gene alteration involving human germ cells, zygotes, or embryos. They also outlaw human cloning "by any means, including somatic cell nuclear transfer, formation of animal/human hybrids, or the transfer of zygotes/embryos between humans and other species." Neither clause stirred much debate, nor did a requirement that researchers disclose to their ethics board "actual, perceived, or potential" conflicts of interest.

To foster compliance, the guidelines attempt to standardize the membership and operations of the estimated 300 to 400 REBs affiliated with universities, hospitals, and research institutes. They also extend the purview of REBs to include a scientific review of all research in the social sciences and humanities. Some researchers, like sociologist Linda Christiansen-Ruffman of St. Mary's University in Halifax, Nova Scotia, find that notion "frightening." She and others fear the imposition of "similar methodologies across all disciplines."

Social scientists were also upset by language that would have barred the use of deception in both surveys and more direct manipulation of human subjects. A blanket prohibition, say officials of the Canadian Psychological Association (CPA), would make it impossible to obtain accurate results in studies like ones on racial prejudice. "If you told everyone right off the bat that this is what we're doing, do you think you would get good information?" asks CPA executive director John Service. "Many would cleanse their opinions to conform to what they suspected were the [questioner's] opinions."

A last-minute threat by SSHRC to withdraw from the exercise led to one more revision of the latest draft, written on 12 May, and the substitution of "waivers" to informed consent. But the waivers would be granted only for research involving minimal risk to the subjects, who would be debriefed afterward "whenever possible and appropriate." The new language borrows liberally from policies at U.S. institutions.

Other provisions were dropped after triggering controversy. Strong adverse reaction to a 1996 discussion paper and two draft versions of the code, for example, forced the councils to retreat from requiring a lawyer on each REB. The councils also dropped a proposal that researchers must obtain both individual and group consent from members of "collectivities" defined as governments, corporations, and native, cultural, religious, ethnic, and social groups. In the final month of deliberations, an MRC ethics subcommittee insisted that the Department of Justice be allowed to vet this idea, and the department objected because affected groups, like aboriginals, hadn't been consulted. Justice also urged the councils to avoid messy liability issues by making universities accountable for such mechanisms as site visits or reporting requirements. Instead, the granting councils will act only after being informed of alleged violations of the guidelines.

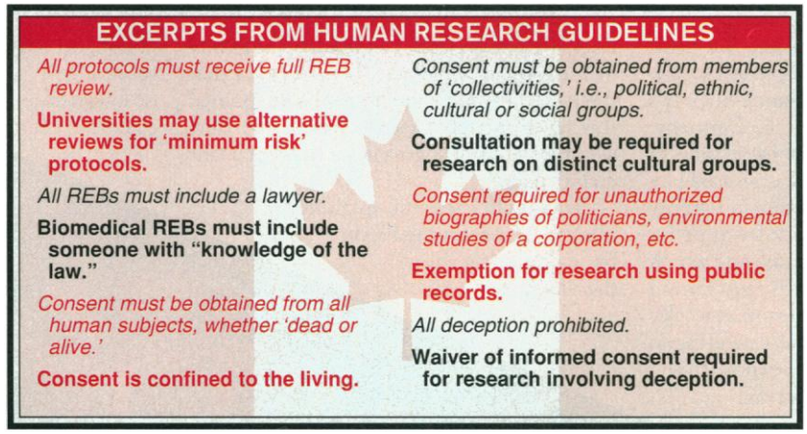
Although the councils say that the new rules are not a formal code, compliance is required for continued funding. Institutions will, however, be able to tailor procedures on a case-by-case basis, giving full REB review to some protocols and less rigorous, expedited review to those deemed of minimal or "everyday" risk.

That latitude has drawn fire. Michael McDonald, a philosopher at the University of British Columbia and deputy chair of the tricouncil ethics working group that drafted the first version of the code, worries that the document "conveys the idea that this is all voluntary and that you can do what you please as long as you set up some kind of committee." Other researchers regard such diversity as a strength and decry what they see as an attempt by one discipline's ethics to carry the day. University of Western Ontario literature professor Frank Davey, for example, says the tricouncil's exercise has been a "top-down, bureaucratic imposition of a biomedical ethics model. ... Many of us live in ignorance and suspicion" of the outcome.

After 4 years of such debate, however, most observers seem eager to move ahead. "We've discussed it at length. Now let's try it out," says Robert Davidson, director of policy and research at the Association of Universities & Colleges of Canada. "Then we can review this in about 2 years to see if all the elements are feasible."

–Wayne Kondro

Wayne Kondro is based in Ottawa.



Fighting words. The final version of the new Canadian ethics code (**in bold type**) skirts language that sank earlier versions (*in italics*).