Issue No. 17

Dissenting voices on accreditation

The authors, members of The Society for Academic Freedom and Scholarship, argue that accreditation will not enhance protections in humanities and social sciences research

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When asked, most people would likely say that human research ethics increase the safety of research subjects. We wish such were the case.

We are all psychologists who have consistently complied with the ethics guidelines of our disciplinary professional organizations—the Canadian Psychological Association and American Psychological Association.

Like us, most Social Sciences and Humanities (SSH) researchers follow the ethical guidelines of their fields and have done so for many years. Further, each of Canada's main federal granting agencies for medical research, scientific and engineering research, and social science and humanities research have had, for some time, their own guidelines that universities followed. The system (largely administered within departments) that brought about this ethical behavior worked quite well long before there was a push to increase the scope of vigilance in monitoring research ethics

About a decade ago the federal government decided to overhaul the oversight of research, for reasons that are still not well understood. In 1997, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects (TCPS) was published. It was the first systematic attempt by Canada's three major granting agencies to provide guidelines covering research in all disciplines and it is Canada's supreme research ethics document.

A painful birth

The TCPS's birth was painful and its labor long, because Canadian researchers identified numerous problems requiring revision. Still, at the time it was published, the focus of the TCPS was almost entirely on research subject safety and appropriate procedures, leading researchers to believe that our goals were shared by the expanding bureaucracy.

If the story had ended with the 1997 TCPS we would have been left with a well-meaning set of guidelines for ethical research, and individual institutions would have continued to monitor research ethics in the manner most suitable for their organizations and the type of research they conducted.

Dramatically increased oversight

What has become apparent, however, is that the TCPS was just the beginning. Since publication of the TCPS, there has been an effort to expand the monitoring process by requiring accreditation of REBs. We argue that this particular move is unnecessary and will be unproductive, especially for SSH research.

Proposals for accreditation have thus far offered no documented benefit to the actual protection of research participants. As such, there is no reason to believe that subjects will be safer as a result of an accreditation agency that is acknowledged to be a very expensive extension of the research ethics enterprise.

Policies may be counterproductive

With respect to accreditation proposals, there has also been no discussion at all as to what will be improved, and how we will know it has been improved, and by how much. By substituting their opinions for evidence, the research ethics industry has for 30 years avoided confronting the ugly fact that their policies may not be effective and, in fact, may be counterproductive.

Unless there is something missing or we have overlooked something here, it appears that accreditation will continue along that gratuitous path and that we will soon have yet more accreditation policies based on the "That sounds like a good idea" defense alone. Indeed, in the absence of serious contemporary ethics violations in SSH, it is odd to impose another

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Dissenting voices on need for accreditation

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layer of bureaucratic control, using as one argument the need to establish best practices to deal with ethical "problems" that no one can document.

Concerns about accreditation

We have several concerns about accreditation policies. First, additional review requirements necessitated by accreditation would mean that SSH research would likely be subject to the same stringent full review required of most medical research—even though the risk involved in SSH research is much lower.

Accreditation affects medical researchers hardly at all; most of their projects have some credible risk and thus warrant full review. However, the additional burden will negatively affect the vast majority of reviews of SSH research.

We have been concerned for some time that medical research is used as the model for all research. There is nothing to indicate that the "standards" developed for accreditation will not further reinforce and impose a one-size-fits-all approach on local Canadian Research Ethics Boards (REBs).

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A second concern, related to the first, is that the more that local REBs feel they must conform and justify the decisions they make to a national body, the more likely they will be to interpret guidelines in the strictest sense. In contrast, the more the local REBs believe they have flexibility in responding to the research they monitor, the more likely there will be better dialogue with the researchers, and, as a result, improved resolution of ethics concerns. Local control is better than distant control.

A third concern focuses on the burden that standardization is likely to impose on researchers. Our belief is that national standards will lead to centralized rules that attempt to cover all cases of possible abuse and this will lead to more cumbersome ethics protocols and approval procedures for all researchers to follow, including those whose research presents little risk to subjects. In the next section, we flesh out some of these concerns with respect to a recent proposal from a federal committee charged with accreditation planning.

In June, 2008, the Canadian government issued "Moving Ahead: Final Report of the Experts Committee for Human Research Participant Protection in Canada," which asserts that lack of central command automatically means the system doesn't work, or doesn't work optimally, because it is governed by a patchwork of regulations developed "by a variety of agencies and organizations, operating under various jurisdictions and mandates and, by and large, independent of one another. Over the course of the past decade or so, governance measures have been put in place by a number of players, each acting in the best interests of research participants, but resulting in a 'non-system'. . ."

No claims of research subject jeopardy

Note that the committee did not claim in its report that research subjects' safety has been jeopardized. Instead, it argues that the system is not neat. The proposed system of accreditation to make it neat will be a researcher's nightmare, administered by an agency with an annual budget of $9-10 million and a staff of 51.

The process would include site visits to review the organization, administrators, REB members, and researchers. The reviewers would attend REB meetings, examine its minutes, the decisions taken, review the educational materials and requirements for education for participant protection, and eventually submit a report to the Accreditation Panel for a decision.

Accountability to researchers

Sadly, there is no mention of REB accountability to researchers, of appeal processes available to researchers, of plans for evaluation research to show that REBs enhance research participant safety, or of evidence that the accreditation process would benefit researchers.

Rather than setting up an accreditation process, it would be much more useful if the ethics industry would spend its time focusing on facilitating research and dealing with genuine participant safety issues in research ethics, hence, avoiding creating a new set of ethics problems that derive almost entirely from the desire for centralized bureaucracy.

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Levine, Fost raise questions about accreditation

"Many requirements imposed by . . . the accreditation process, have little relationship to the protection of human research participants"

Robert J. Levine and **Norman Fost** wrote an editorial in *The Journal of the American Medical Association* (*JAMA*, 2007; 298 (18): 2196-2198) arguing that "Many requirements imposed by federal agencies, and now by the accreditation process, have little relationship to the protection of human research participants."

Both Levine, Yale University Professor of Medicine, and Fost, University of Wisconsin Department of Pediatrics, have received lifetime achievement awards in recognition of their work in protecting human subjects, including awards from OHRP. Together they have 61 years experience as chairs of IRBs.

They said "The increase in the IRBs' burden is not entirely the responsibility of federal oversight agencies. Part of the problem is self-inflicted, as academic medical centers shifted responsibility for IRB structure and function to senior institutional officials, often with little IRB experience, who made a political judgment that, in order to avoid sanctions, the prudent course was to impose requirements on the system that are even more stringent than those of the regulatory agencies."

"In addition, a small number of unanticipated deaths of research subjects at prestigious medical centers . . . became causes cèlébres. Even though the relationship of these unfortunate events to IRB responsibilities is uncertain at most, their reporting reinforced cries that the entire system was broken.

"Clearly, the recent demands for increased bureaucratic procedures and their documentation would not have prevented any of these episodes.

Increasing focus on minutiae

"To the contrary, the increasing focus on minutiae has been distracting IRBs from more important substantive issues. Inflexible requirements for adherence to narrow interpretations of every word in regulations and other policies have led to a system that is more concerned with protection of the institution than protection of human research participants.

"The sources of these problems include OHRP and the FDA because they appear to threaten institutions with draconian penalties for minor infractions; institutional (university and other) administrators acting out of fear that their institution could be the next to have its entire research operation suspended by 'getting caught' in one of these minor infractions; and credentialing and certifying agencies for supporting these excesses by including them in their criteria for accreditation."Δ

Ethics resources

Moving Ahead—Final Report of the Experts Committee for Human Research Participant Protection in Canada (June 15, 2008)
http://www.hrppc-pphrc.ca/english/movingaheadfinalreport2008.pdf

Mueller, J. H. (2007). "Ignorance is neither bliss nor ethical." *Northwestern University Law Review*, 101, 809-836

Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects.
http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf

The Society for Academic Freedom and Scholarship (SAFS)
http://www.safs.ca

The Alden March Bioethics Institute maintains a comprehensive listing of conferences, educational programs, and other activities related to research ethics and related issues. See **http://www.bioethics.net/events.php?page=1**

For a listing of bioethics news generally, see the institute's site at:
http://www.bioethics.net

Bioethics blog, written by the editors of *The American Journal of Bioethics*
http://blog.bioethics.net/

Women's bioethics project
http://womensbioethics.blogspot.com/