July 29, 2002

Interagency Advisory Panel on Research Ethics (PRE)
CIHR, NSERC, and SSHRC
Ottawa, Ontario, secretariat@pre.ethics.gc.ca

Dear PRE Panel Members:

We are a national organization dedicated to scholarship. I am writing to you to let you know of our serious concerns regarding the proposed national governance system for the ethics of research involving humans. We believe the proposed regulatory system will greatly increase the burdens on individual researchers and university administration with little or no benefit to the genuine protection of research participants.

Our understanding is that the Interagency Advisory Panel on Research Ethics (PRE) was created, in November 2001, by the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council. The PRE's plan for governance of research ethics that we used as our reference is described in an Executive Summary available on-line at:

http://www.nserc.ca/programs/ethics/english/pre_e.htm

The current status of this plan appears to be a document available on-line at the National Council on Ethics in Human Research, at:

http://www.ncehr-cnerh.org/downloads/FIN_TaskForceReport_EN.pdf

We are responding to a call for comments, although the document, dated March 29, 2002, is entitled "Final Report" and will be referred to as such here.

Although this scheme has been in development for some time, only recently has the existence of the plan, much less its specifics, begun to circulate beyond the confines of the PRE and its immediate contacts. An examination of the two documents listed above raises many concerns about the process itself and the implications of the plan for freedom of inquiry. For example, the plan:

- does not establish any need for a national governance system
- does not make it clear that there will be any benefits to researchers
- provides no assessment scheme to document the benefits to public safety
- uses a medical research model which is not applicable to research in general
- is unclear on even the mechanics of accreditation and national governance
- aims to extend coverage to private sector research, again with no justification
- suggests that socially desirable outcomes are the aim of research
- has been developed by a top-down process driven by insiders and bioethicists
- has had no meaningful input from the community of individual scholars
- continues to download the expenses to the local institutional review boards
- seems guided by the premise that more control is inherently good

We elaborate these concerns below:

1) Neither the Executive Summary nor the Final Report has documented the need for national accreditation. A handful of problems are noted; however, none of these would have been prevented had national accreditation been in place in the past. Thus, the existence of these problems is irrelevant when used as an argument for introducing a national accreditation system. We also note that although this report is intended to cover all research involving humans, neither this report nor any other has yet to cite a single example of a problem stemming from a non-medical (i.e., behavioural) research project.

Further, although the Executive Summary indicates that, "an accreditation program should … be subject to performance evaluation, including independent auditing," there is nothing in the report to establish how we will ever know whether this added layer of bureaucracy has added value to public safety compared to the pre-accreditation era. What is clear is that such a national governance plan will further complicate the pursuit of scholarship, and thus potentially compromise the independence and integrity of Canadian research. In essence, there is not only no concrete evidence of the need for such a scheme, there is no concern about directly demonstrating enhanced public safety. The proponents of this change have the burden of showing why this is needed and how we will know it worked. It is not enough to assert that it will make the world a kinder, gentler place.

Ostensibly in the category of accountability, the plan proposes having the national governance body report to the Auditor General. The rationale for this is unclear; in fact, it seems that this recommendation was based on a process of elimination rather than any true justification for assuring the integrity of scholarship. This is just one of many ambiguities that indicate the scheme is not well conceived.

2) The plan in question has been developed by individuals whose background is in medicine, and by others who have made a career of bioethics, as demonstrated by the biographies of the task force members and the groups who were invited to make presentations to the task force. Two results follow directly. First, the discussion is entirely about the control of inquiry and constraints on inquiry, and never about freedom of inquiry. The agendas of control of inquiry and freedom of inquiry seem to have become "two solitudes" in the research ethics industry, with the latter completely subservient to the former. The main justification seems to be simply that "accreditation (regulation) is desirable in all things," which is a value system unrelated to either scientific integrity or public safety.

3) The second result is that the plan takes health research as the model for all research. Although the plan's discussion claims to have incorporated input from "a diversity of research interests" and "a balanced representation of researchers," only the "clinical trials" drug-testing model is present throughout.

Whether this plan would accomplish anything for medical research is certainly a reasonable question, but even if it did it would still be a completely open question as to whether it would ever accomplish anything for non-medical research. The "clinical trials" paradigm is essentially Consumer Reports style testing, that is, product testing, and thus it lacks the epistemological theory testing and theory building character of research in other traditions of scientific inquiry.

Further, the mixture of profit with medical research outcomes, as witness the document's preoccupation with the benefits for the pharmaceutical industry, for example, is not typical of scientific inquiry in general. That the further investment of local resources might result in further benefits for the drug industry hardly seems a compelling reason to burden scholars in all disciplines, given that the diversion of local resources means that other, usually already underfunded, programs will suffer even more.

4) The plan is quite vague on who or what will be accredited, and just how accreditation will be achieved. It is also vague on what the consequences of non-accreditation would be.

The plan is also ambiguous in many other respects, for example, describing accreditation as "voluntary" but "required" (or "legislated") in the same sentence. The failure to see the contradiction in that should give us all pause as to just how complete the control agenda will become under the proposed national governance scheme. Given that freedom of inquiry is never mentioned, it seems justifiable to conclude that the agenda on control of inquiry is far from finished.

5) The plan envisions expanding coverage to many additional realms, such as the private sector. Nonetheless, there is no evidence presented that research participants are now at greater risk in private-sector research than in public-sector research, just as there was no evidence that subjects were safer in federally sponsored research on campus than in non-supported research some years ago. The fact that the need is not established in the report strongly suggests that it does not, in fact, exist.

Further expansion of control of research outcomes is also projected. For example, the plan identifies "cultural integrity" as a desired outcome, as well as "research important to society." These are matters of ideology, and the intrusion of such values into the research review process provides a mechanism for censorship of unpopular research and scholarship, matters quite unrelated to public safety. Our concerns here are reminiscent of the concerns expressed by many critics of the original Tri-Council Policy Statement on research ethics, who pointed out that ethics committees are ill-suited to make statements about the scientific or scholarly merit of research projects and when they do so they improperly interfere with the peer-review system that has served science and society so well. Ethics committees should stick to their primary job of judging the potential harm that might be done to research participants and avoid making epistemological statements about the proposed research. Our fear is that the increased control of research through centralized and inflexible ethics review systems will increase the likelihood that ethics committees will stray into areas of judging scientific worth.

History has seen several eras demonstrating that the promotion of such central control of research and scholarship not only ultimately fails, but also distorts the process of inquiry beyond rational recognition. Such ideological criteria (sometimes masquerading as epistemological ones) distract young investigators from the more appropriate goals of scientific inquiry; and, more generally, the use of such biased criteria will compromise the perceived integrity of Canadian research worldwide, with absolutely no demonstrable enhancement of public safety. Again, the premise seems to be that control is good in and of itself, whereas freedom of inquiry is an afterthought, at best. There is no evidence that the amount of control presently in place is justified, much less that any more would be beneficial.

6) A report to the Law Commission of Canada is noted, contrary to fact, as if it were the official position of the LCC, though the LCC web site still identifies it as "the opinion of the author". This elevates personal opinions to the status of policy in a completely gratuitous fashion.

7) Although the accreditation process is self-described as "transparent and inclusive," it is hard to see evidence for that in these documents. Instead, the reality seems to be that it has been and will continue to be a sequestered and opaque process, with exclusive or privileged input by like-minded control-oriented constituencies, bypassing the large community of individual researchers and scholars. The process has been extremely top-down, and driven by the insider concerns of the professional bioethics community. There is no evidence that researchers have indicated the need for any of this. Thus, in spite of what is written in the report, there will be no “buy-in” from the great majority of the research community. In recognition of this fact, the report does not even attempt to suggest in Section 9.0, entitled, “What are the benefits from an accreditation program?” that there will be any benefits to researchers. The report’s authors clearly understand that there will be virtually none.

The plan notes that membership on the Board of Accreditation is to include those who show "... genuine support of the Board's mission." At least this part is clear or transparent: “no dissent allowed,” which does not seem a desirable attitude for either governance or research.

8) The costs for this added layer of bureaucracy are again to be assumed by the local institutions, downloading yet more expenses in an exercise designed to solve a problem that is not demonstrated to exist, with no process in place to verify a benefit to public safety. This is an unreasonable demand on the budgets of local institutions, given the failure to document the need and the absence of a mechanism to document value added. Furthermore, such downloading continues the tradition of staffing review boards with volunteers, which encourages the introduction of private agendas unrelated to the integrity of scholarship.

These are some of the concerns that lead us to conclude that not only is this accreditation plan not demonstrably needed, it is ill-conceived, and the process whereby it emerged is not likely to produce an appropriate plan. It appears solely intended to further control of research at the expense of freedom of inquiry, and in no way does it produce a demonstrable gain in public safety.

We hope these comments are helpful to you in improving both the substance and the process related to the current PRE document. You may recall that it was only because of vigorous and persistent responses by researchers, universities, academic and professional associations that the original Tri-Council Statement on Ethical Conduct for Research Involving Humans was forced to undergo several revisions that considerably improved the document from its original form.

Unfortunately, we believe that such sustained attention is once again required to bring the proposal for this new research ethics regulatory body to a version satisfactory to researchers, universities, and the public.

Sincerely,
Clive Seligman
President