"Moving Ahead" or "More of the Same"?

Comments on the *Draft Report of the Experts Committee for Human Research Protection in Canada*

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Thank you for the opportunity to comment on *Moving Ahead: Draft Report of the Experts Committee for Human Research Protection in Canada*. Our submission will respond directly to the questions you pose.

1. How well is the Canadian system for the protection of human research participants currently functioning? What are some of the most pressing concerns or challenges? What elements are working best?

We doubt you can make any overall characterization of how the system is working. It seems to be working for some researchers and some kinds of research and not for others. It appears to work best for more experimental research involving "research subjects" with whom the researchers have a transient and detached relationship, and for clinical trials and other biomedical research that is highly structured, paradigmatic and regulated (other than that researchers in those domains want faster turnover, greater consistency, and the ability to do one-stop shopping for multi-centre trials). However, the current system is very *poorly* suited for and does *not* work well for research in the social sciences and humanities, and particularly research that is more critical, qualitative and field-based.

2. Is there need for improvements in the system? If yes, for what reasons? What are the most pressing aspects of this need (policy, standards, education, monitoring, accreditation, sanctions, other)? What might be some of the consequences if the status quo remains in place (e.g., for multi-jurisdictional research, policy harmonization, education, and participant protection)?

There are many areas where improvement is necessary:

- Academic freedom of social sciences and humanities researchers must be far better protected from REBs that have become instruments for liability management and *a priori* censorship.
- The "one size fits all" model of ethics review that the TCPS represents is faulty at its core and should be rejected.
- The structure of REB membership outlined in the TCPS is ill-suited for the variety of non-experimental research that goes on in the social sciences and humanities and creates a situation whereby non-experts – people who know no more about marginalized groups than they read in the newspaper, and people who have less familiarity with the methods being utilized than your average social science undergraduate – are given the power to stop ethical research and even unknowingly impose *un*ethical requirements because of their lack of expertise.

- There is far too much power invested in REBs and far too little accountability; REBs can violate policy and impose ridiculous and unethical resolutions in a moment, and it can take 18 months of effort on the part of the researcher to undo that damage.
- This sort of double standard continues at every level. Notwithstanding the TCPS injunction against institutional conflicts of interest, university ethics policies across the country allow far too great a coziness between administrative wings of the university and REBs; university administrators who resign from direct involvement in their university REBs because of the obvious institutional conflict of interest are then welcomed on the PRE; injunctions in the TCPS to recognize disciplinary standards and maintain REB memberships that reflect the diversity of research done in the institution remain empty promises. On this latter point, we note the same problems are evident in the Sponsors Table and Experts Committee – although about 70% of the researchers in the country are social science and humanities researchers, where and to what extent are they represented in your process? Once again we see a biomedically heavy committee that is simultaneously overrepresented with university and research administrators offering solutions that make some sense within a limited range of biomedical and experimental research and no sense whatsoever for the majority of researchers and research that is done in Canada. And once again we see proposals that may have applicability to the narrow range of research interests the majority members of the Experts Committee represent, but would be disastrous if applied holus bolus to everyone else.

The second part of your question assumes there *is* a status quo, but whether one exists or not depends where and how you look. Rather than a stationary status quo, one could make the argument that Canada's ethics regulatory structure is evolving. There are processes in place through PRE and SRE that have been ongoing for the years it takes to gather information, diagnose problems, consult with research communities and recommend solutions. These appear about to come to fruition within the next year. Whether they do or not is another question, and whether PRE and the Presidents of the Granting Councils ultimately bury their heads in the sand or do something positive remains to be seen, but your timing is poor – PRE and SRE should be given enough rope to hang themselves and that involves seeing what their processes will generate. If they fail at that point, alternatives should be advanced, but to bring in an entirely new plan before PRE/SRE have been given a chance to deliver on their mandate would be an incredible waste.

That said, even if we presume the worst case scenario and accept that PRE/SRE will do nothing more than rearrange the deck chairs, it requires a leap in logic to conclude that the approach proposed by the Experts Committee will somehow solve all the problems. In fact, we believe quite the opposite is true; the solution offered by the Experts Committee is even *more* flawed than the current system in terms of the impact it will have on the full range of research done in Canada, and particularly to non-experimental research in the social sciences and humanities.

3. How would you assess the arguments and recommendations of the report* Moving Ahead*, in particular, that an independent organization be created with the three primary functions of policy, education, and accreditation?

The idea of a centralized organization and bureaucratic structure, whether independent or not, is the wrong model for the social sciences and humanities. Effective ethical consideration and review in the social sciences and humanities require specialized knowledge and understanding of context that is exactly what vanishes when you impose a centralized bureaucratic structure, and that is the fundamental flaw of the model the Experts Committee offers. The proposed structure might work reasonably well with highly paradigmatic experimental and biomedical research that works within a very confined regulatory structure, but would be a disaster for the diverse paradigms, topics and contexts that characterize social science and humanities research.

The one redeeming feature we see of the accreditation model is the door it opens to REB accountability. However, we would distinguish between REB accountability and accreditation. The accreditation model is only one way through which REB accountability can be achieved and, all things considered (as should be clear from the rest of our comments in this submission), we believe that the creation of an even more bloated and more centralized bureaucracy (as the ST/EC proposal describes) will create more problems than it solves in relation to the social sciences and humanities.

4. What would be the impact (positive and/or negative, including financial) on you and/or your organization were an organization similar to the one proposed in the report Moving Ahead be established? Are there alternative courses of action that you would recommend?

The effect would be disastrous. The *Moving Ahead* document offers little more than a minor variant of the Office of Human Research Protections model that operates in the United States and that social science and humanities researchers in that country have been reeling from for more than a decade. Everything we hear from U.S. colleagues tells us that the model the Experts Committee proposes in *Moving Ahead* creates inflexible review structures because institutional review boards become obsessed with following rules regardless of their relevance and ethical probity because no one wants to do anything that would undermine accreditation status. But that is liability management, not ethics.

The alternative course of action we would recommend is complete rejection of the "one size fits all" model and that, for starters, strictly biomedical, clinical trial, and formally experimental research involving "human subjects" (and all that implies in terms of the nature of the relationship between researcher and the person who is subjected to the researcher's procedures and interventions) should be carved off and create its/their own structures and institutions, one of which might well be the accreditation/bureaucratic structures proposed by the Experts Committee. With that burden removed from the rest of the research community, the rest of us should scout the landscape, see who is left, and commence our own discussion about what sorts of structures and processes are most appropriate.

5. What issues were not addressed in the report* Moving Ahead *that need to be considered?

Pretty much everything we've stated above. The *Moving Ahead* document is presented as something fresh and different when it is nothing but more of the same – it does not question the one-size-fits-all model; it re-creates the biomedical/experimental dominance and resulting singularity and myopic vision that characterizes the TCPS; it further centralizes bureaucratic power instead of making it more decentralized and disciplinary- and context-sensitive; and it is produced by a group of people who do not represent the diversity of the research enterprise

in Canada. The phrase “academic freedom” never appears once in the document. There is no discussion of the weaknesses and limitations of the similar accreditation system that operates already in the United States. There is a provision made for a review but as outlined it is an “elite” review by people who will have a vested interested in defending the system they’ve put in place; incredibly, there is no provision for incorporating researchers and research participants into the review process.

6. Looking at what could be done right now, or in the near future, what specific actions would you recommend to improve the protection of human research participants? Who should pay for what share of the financial costs in any change to the system (e.g., policy, education, accreditation as cost recovery)? In the short to medium term during a potential transition? In the longer term?

We’ve addressed the “what to do” issues above. Beyond that, you’re asking us to cost out something we completely disagree with. Rather than creating an even more bloated bureaucracy fraught with institutional conflicts of interest, if one were serious about helping research participants we would put money into promoting more statute-based protections for research participants (e.g., to protect research confidentiality) and encourage universities to put money in a legal defense fund that could be used in cases that would protect and assert research participant rights. Beyond that we would recommend: (a) that SSHRC and the Canadian Federation for the Humanities and Social Sciences withdraw from the Sponsors Table/Experts Committee process because their presence only adds an aura of legitimacy to what is a fundamentally flawed exercise; (b) that clinical trial, manipulatively experimental and related research that is strictly biomedical be partitioned from the rest of the research enterprise and form its own processes of review and regulation; and (c) that the social sciences and humanities communities and those parts of the medical/health community who engage social science and/or humanities research techniques and approaches be encouraged to sit down and develop their own regulatory scheme in a way that is more sensitive to context and does not undermine academic freedom for reasons that have nothing to do with ethics.

Conclusion: Moving Ahead *Should Have Been Titled* More of the Same

While the accreditation model contains the positive element of creating a mechanism for REB accountability, the accreditation model is only one way through which REB accountability can be achieved and, all things considered, we believe it is the wrong one and that it will only create more problems than it solves in relation to the social sciences and humanities. We also see this as yet another classic case where something that might make sense for one domain of research – particularly, in this instance, for purely biomedical, clinical trial and manipulative experimental research that is very paradigmatic and (in the case of clinical trials) highly regulated -- would create a disaster for the research enterprise as a whole, and be particularly disastrous if applied to the social sciences, humanities, and creative arts.

The root problem for us lies in the premise that guides the TCPS and that is never even questioned in the Sponsors Table/Experts Committee accreditation proposal – that a “one-size-fits-all” model of ethics codification and regulation is required for Canada’s diverse research community. Starting from that premise inevitably generates Procrustean solutions that speak far more to where and how power is exercised in Canada’s diverse research

community than to principles of ethics. Seen in that light, the ST/EC report is simply more of the same and will once again result in a small but powerful set of interests within the research community wagging the rest of the community to the detriment of other researchers and the participants who take part in their research. For all these reasons, we are utterly opposed to the accreditation model ST/EC proposes.