
TCPS-2's Enduring Challenge: How to Provide Ethics Governance While Respecting Academic Freedom

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The concerns voiced in our submission regarding the first (Dec/2008) draft of the prospective revision of the *Tri-Council Policy Statement*, referred to here as TCPS2-1,¹ focussed on two inter-related issues: (1) the draft document's provisions regarding privacy and confidentiality; and (2) whether the centralized regulatory ethics regime that TCPS2-1 envisioned did enough to ensure that REBs respect the academic freedom of the researchers they control. TCPS2-2 (the latest draft) has dealt with many, but not all of these issues.

1. Improvements Regarding Privacy and Confidentiality

TCPS2-2 follows the advice of the Social Science and Humanities Working Committee on Research Ethics (SSHWC) on how to approach privacy and confidentiality issues.² Given that SSHWC went through several iterations of drafting and consultation in order to build a national consensus, TCPS2-1's incorporation of a very different philosophy to SSHWC's recommendations was disturbing. TCPS2-2 is a notable improvement. Nonetheless, it is surprising that no mention is made of how researchers can use the common law Wigmore test to protect confidential research information. After all, the Supreme Court of Canada has recognized this test as the appropriate mechanism for a case-by-case basis adjudication of claims of evidentiary privilege (*Slavutych v. Baker et al.*, [1976] 1 S.C.R. 254.). If the purpose of the TCPS is to protect research participants, then it should encourage researchers to design sensitive research with the Wigmore criteria in mind. As far as we know, neither PRE/SRE nor the three granting councils have shown any interest in lobbying the Federal government to enact a research shield law like the certificate of confidentiality³ system currently operating in the U.S. In lieu of such an effort, the TCPS should at least advise researchers of the one mechanism they can employ to try to protect confidential research information in court.

¹ In this submission the Tri-Council Policy Statement currently in effect is referred to as TCPS-1, while its prospective replacement is referred to as TCPS-2. The first draft of the prospective revision (released for consultation in December/2008) is referred to as TCPS2-1. The second and more recent draft (released for consultation in December/2009) is referred to as "the current draft" or TCPS2-2.

² "SSHWC Recommendations Regarding Privacy and Confidentiality" (2008)
<http://www.pre.ethics.gc.ca/eng/resources-ressources/reports-rapports/sshwc-ctsh/>

³ <http://grants2.nih.gov/grants/policy/coc/>

2. REB Accountability: TCPS2-2's Governance Model Continues to Threaten Academic Freedom

As it stands TCPS2-2 still does not include enough protection of academic freedom. Its provision of greater discretion to REBs for delegation of minimal risk projects at more decentralized levels of an institution is a positive step to the extent it helps to ensure that persons with expert knowledge of the methodological and substantive issues involved in any given project can provide meaningful review.

Although TCPS2-2 has abandoned some of the reasoning offered in TCPS-1 in favour of a new framework, it is unfortunate that the following TCPS-1 passage concerning some of the prerequisites for meaningful ethics review has been omitted, as it stresses the importance of contextual knowledge in identifying and addressing ethical concerns, and of recognizing disciplinary standards in their resolution:

For meaningful and effective application, the foregoing ethical principles must operate neither in the abstract, nor in isolation from one another. Ethical principles are sometimes criticized as being applied in formulaic ways. To avoid this, they should be applied in the context of the nature of the research and of the ethical norms and practices of the relevant research discipline. Good ethical reasoning requires thought, insight and sensitivity to context, which in turn helps to refine the roles and application of norms that govern relationships (p.i.9)

Part of the difficulty with TCPS-1, which thus far has been repeated in TCPS2-1 and 2-2, is that the policy's overall governance model is not consistent with these very reasonable requirements for meaningful and effective ethics review. For example, TCPS2-2 repeats the TCPS-1 requirement that REB composition include:

- (a) at least two members [who] have expertise in relevant research disciplines, fields, and methodologies covered by the REB;
- (b) at least one member is knowledgeable in ethics;
- (c) at least one member is knowledgeable in the law (but that member should not be the institution's legal counsel or risk manager); and
- (d) at least one community member who has no affiliation with the institution.

But if "meaningful and effective" application of ethical principles requires them to be "applied in the context of the nature of the research and of the ethical norms and practices of the relevant research discipline," then even if the two members who "have expertise in relevant research disciplines, fields, and methodologies covered by the REB" are competent across the full range of methods and content across the university – something we have yet to see in any REB with which we are familiar – the majority of REB members still would not be competent to engage in "meaningful and effective" decision making.

Although, like its predecessor, TCPS2-2 allows for it, it does not actively promote a multiple REB system in a single institution. TCPS-2 should encourage multiple REBs, particularly in larger institutions, because the review process will be inherently flawed if most REB members know little about the context in which certain kinds of proposed research will occur, or do not have the substantive understanding to know what risks exist or what the discipline-based best practices are for dealing with the issues that any given discipline commonly encounters. For example, it is very common for criminologists to deal with justice system personnel and various stigmatized deviant and/or offender populations. Our experience is that

REB members often view interviewing persons from these walks of life as inherently dangerous. The only knowledge many REB members have about such persons and the milieus in which they operate is based on stereotypes that are no more sophisticated than would be held by the average person in the street. We have seen REB members take offence at the presence of representatives for VANDU (Vancouver Area Network of Drug Users) who were invited by a researcher to help the REB by offering a participant perspective on the proposed research. While ideally an REB would provide a forum in which to discuss ethics issues, REBs dominated by members who have no specialized knowledge of the practices in a particular discipline can undermine the integrity of ethics review and, all too often, make it a process to be undertaken and survived instead of a discussion to be welcomed. The fact that many academics will make such adjudications notwithstanding their lack of expertise greatly concerns us; the fact that TCPS2-2 appears to condone and even encourage this practice concerns us even more.

TCPS2-2 seems to try and address this problem of expertise in two ways. The first involves creating separate chapters that are designed to outline ethics policy issues in certain unique areas. But will creating a chapter on qualitative methods make the experimentalist from computing science or psychology an authority on qualitative method ethics issues? It is no more likely that the chapters on clinical trials and human genetic research will make us sufficiently expert to adjudicate proposals coming from our kinesiology department or health sciences faculty. Academics would raise their eyebrows if someone said “but I’ve read a chapter on it” to justify their application to teach a course or to declare themselves an expert in some area – in which case why would we see it as sufficient expertise to make decisions about other people’s research? Stated simply, if an REB member’s understanding of an area is so deficient that s/he needs to read the chapter, s/he should not be adjudicating proposals that utilize those methods (in the case of qualitative methods) or involve those topics (in the case of Aboriginal issues, clinical trials, human biological materials, and human genetic research).

Another way that TCPS2-2 addresses the member competence problem is to encourage the use of *ad hoc* advisors when the expertise on the REB is inadequate. This mechanism is problematic in two respects. First, it is likely to be used inconsistently across institutions. One fears the REBs that *should* use it most will be the ones that use it least. Second, while TCPS2-2 states that more frequent use of such advisors is a sign that membership on the REB should be adjusted to deal with such proposals, the end result might be to make large committees even larger. The SFU REB, for example, which has often been the focus of complaint because of the dearth of individuals who can reasonably claim experience with qualitative research, already has 14 members. Would it not be more reasonable to split the group into two separate Boards - or three - that can bring a more focussed expertise to different research traditions and substantive areas, or come together on those occasions where a given proposal calls for a bridging of disciplines? Indeed, one way for TCPS-2 to encourage multiple REBs would be to suggest or impose a maximum committee size (e.g., of 10); if greater numbers are required to maintain appropriate epistemological/substantive coverage, this would be taken as a sign that more committees are warranted.

3. Other Issues

Other concerns listed in the order in which they appear in TCPS2-2 include the following:

- 3.1. Lines 215-219 state that, “An important threat to justice is the imbalance of power that often exists in the relationship between researcher and participant. Participants will generally not understand the research in the same way and in the same depth as does the researcher. Historically, there have been instances in which this power imbalance has been abused, with resulting harm to participants.” This statement is truer of research in the clinical and experimental domains than it is in the bulk of the social sciences, and especially with respect to field-based research. In some community-based research very often it is the researcher who has less power because of the dependence the researcher has on gatekeepers to allow access to a community of interest. For example, in recent years we are seeing more field settings where gaining access to research participants is contingent on some demonstration that the researcher will cast certain activities in a positive light and support *status quo* approaches. This problem characterizes much research commissioned by federal and provincial governments. In any event, lines 215-219 should be changed to recognize the diversity of power relationships in different research contexts; this could be done most easily by changing the “often” in the first line to “can” or “sometimes.”
- 3.2. Line 248 reads “and may be comprised of constitutional, statutory, regulatory, common law...” It should read “and may comprise constitutional, statutory...”
- 3.3. Lines 621-624 note that, “Certain accepted research paradigms bring inherent limitations to the prior identification of risk. For example, when research in the social sciences employs emergent design, the manner in which the study will proceed and any associated risks may be known only as the study unfolds.” This paragraph is written in a manner that encourages REBs to see “emergent design” as somehow threatening. In our experience, although the design itself may be emergent, risks posed by the intended research rarely shift dramatically. If anything, emergent designs are less threatening because they allow both researcher and participants to determine and establish mutually respectful comfort levels before and as they proceed with the research.
- 3.4. TCPS2-2’s allusion in Chapter 4 to “over-protectionist” attitudes on the part of some REBs (starting at line 1366) is well-placed and important. This is an appropriate point at which to state that REBs should be required to demonstrate that a risk is substantial and reasonably likely before requiring a researcher to take it into consideration. In our experience, REBs that do not possess the necessary competence to adjudicate proposals often engage in “what if” scenarios that do nothing more than reflect the REB’s ignorance of what “really” goes on in the settings we research. In a paper on ethics and the governance of criminological research in Australia, Mark Israel observed: “HREC⁴ discussions of risk occur in an empirical vacuum – imaginative and risk averse committees can envisage a vast array of speculative harms, over-estimate risks, and require researchers to respond to

⁴ Human Research Ethics Committee

subjectively-assessed worst-case hypotheses.”⁵ This problem would be less of an issue if REB member expertise were to be dealt with in the way suggested in section 2 above, but if it is not, then the problem of abstract “what if” scenarios should be addressed by stressing that risks must be reasonably foreseeable and substantial before they are introduced into a risk-benefit analysis of a particular research proposal, or mentioned in a consent statement.

3.5. Although TCPS2-2’s chapter on privacy and confidentiality is a considerable improvement over TCPS2-1, the new draft’s treatment of conflicts of interest that arise in relation to privacy and confidentiality when a person has both “researcher” and “professional” roles takes a different stance than TCPS-1, which stated:

Article 2.4(e) reminds researchers of relevant ethical duties that govern potential or actual conflicts of interest, as they relate to the free and informed consent of subjects. To preserve and not abuse the trust on which many professional relations reside, researchers should separate their role as researcher from their roles as therapists, caregivers, teachers, advisors, consultants, supervisors, students or employers and the like. If a researcher is acting in dual roles, this fact must always be disclosed to the subject. Researchers should disassociate their role as researcher from other roles, in the recruitment process and throughout the project. (p.2.8)

In contrast, TCPS2-2 suggests:

The ethical duty of confidentiality must, at times, be balanced against legal or professional requirements, or competing ethical considerations, that call for disclosure of information obtained or created in a research context. For example, in exceptional and compelling circumstances, researchers may be subject to obligations to report information to authorities to protect the health, life or safety of a research participant or third party. (lines 1732-1737)

While the reference to legal requirements is sound, conflicts of interest arise when a researcher wears two professional hats. Professionals who also conduct research should be prepared to adopt research ethics guidelines, not subvert ethics principles because of their inability or unwillingness to separate their professional roles and obligations. In this regard, TCPS2-2 could be seen to encourage researcher/professionals to act on their conflict of interest instead of resolving the conflict in favour of the rights of participants.

For example, some years ago Ivan Zinger, who was at that time both a doctoral student in psychology at Carleton University and an employee of Correctional Services of Canada (CSC), conducted his dissertation research on the effects of “administrative segregation” (solitary confinement) on prisoners.⁶ The study’s intent was to resolve a controversy as to whether solitary confinement makes prisoners more aggressive toward themselves and others. However, in keeping with his “professional requirements” as a CSC employee, Zinger told prisoners that, if they indicated any propensity for violence or plans to escape, he was “required” to disclose this to prison authorities. Not surprisingly, offenders reported little propensity for violence. This finding led Zinger to conclude that CSC’s

⁵ Israel, M. (2004). *Ethics and the Governance of Criminological Research in Australia*. Sydney: New South Wales Bureau of Crime Statistics and Research
[http://www.lawlink.nsw.gov.au/lawlink/bocsar/ll_bocsar.nsf/vwFiles/R55.pdf/\\$file/R55.pdf](http://www.lawlink.nsw.gov.au/lawlink/bocsar/ll_bocsar.nsf/vwFiles/R55.pdf/$file/R55.pdf)

⁶ See Zinger, I., Wichmann, C., and Andrews, D.A. (2001). “The effects of administrative segregation.” *Canadian Journal of Criminology*, 43(1): 47-83.

policies were humane and unproblematic. Although criticized in the literature⁷ because his findings could well have been an artefact of his limitation of confidentiality, of greater concern is that TCPS2-2 appears to condone such role conflicts instead of requiring that they be resolved.

- 3.6. Article 6.18 outlines appeal procedures for negative REB decisions. Included (at lines 2611-2618) is a list of grounds that a researcher might invoke when appealing an REB decision. This section should include “violation of academic freedom” as a ground for appeal when the researcher believes that an REB is imposing its own “right answer” when other equally ethical resolutions are possible. The new TCPS should explicitly state that REBs must understand that there may be more than one ethical way to deal with any given situation. The question the REB should ask is not “Does the REB agree with whatever the researcher proposes?” but simply, “Is what the researcher proposes consistent with the policy?”
- 3.7. The revised draft policy notes several situations (at lines 2885-2892) in which institutions might be in a conflict of interest that affects the rights and interests of participants. Another example would be useful here, that being when what Goffman referred to as “total institutions,” such as prisons and mental hospitals, have ideas about control that may conflict with the rights and interests of those under their control. TCPS2 should include protections of research participants in total institutions along the lines of those that now exist in the United States regarding prisoners, where REBs overseeing prison research must ensure that at least one of their members is a prisoner representative, and that a majority of the members of the REB (other than prisoners) have no affiliation with prison authorities.⁸ The same principle could be applied, *mutatis mutandis*, to research in other total institutions.
- 3.8. At lines 3051-3056 there is a suggestion that some conflicts of interest arise after the research is complete, and gives the example of a company offering to ghost-write a paper to which a physician-researcher simply signs his or her name. Surely such a practice is unethical because it involves a person claiming authorship for something they did not write, while simultaneously misrepresenting the real authorship of the paper?
- 3.9. Michael McDonald makes many pertinent observations in his commentary on TCPS2-2,⁹ several of which are worth specifically reinforcing:
- a) The “Mandate of the Agencies” section (Lines 20-27) should include a statement that institutions funded by the granting agencies must make reasonable efforts to support researchers who, in good faith, act in accordance with the principles set out in the TCPS. We believe that PRE and SRE should do the same – and that if they do not see this as within their mandate, they should lobby to have their mandates modified to allow them to provide such support.

⁷ See Palys, T.S., and Lowman, J. (2001). Social research with eyes wide shut: The limited confidentiality dilemma. *Canadian Journal of Criminology*, 43(2), 255-67

⁸ See for example, <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.306>

⁹ http://www.noveltechethics.ca/pictures/File/Health_Policy/TCPS_2010/comments_MM.pdf

- b) The TCPS should say that there is a compelling public interest in social science research that is critical of political and corporate institutions (lines 657-665).
- c) Regarding privacy and confidentiality (lines 1749-52) the TCPS should state that institutions are expected to support researchers in their efforts to maintain confidentiality.
- d) To avoid conflict of interest, it is imperative that there be a procedure independent of an institution's administration for appointing, renewing and removing REB members (lines 2231-2238). We have seen instances where a university administration has manipulated REB membership to suit its purposes.
- e) Appeal boards (lines 2592-98) should similarly be constituted through an arm's-length process.