

Comments on Draft SFU Research Ethics Policy R20.01

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My name is Ted Palys, and I am a Professor in the School of Criminology and an Associate Member of the Department of Indigenous Studies at SFU. I was hired to and continue to teach research methods at both the graduate and undergraduate levels, and my expertise includes an expertise in research ethics issues, which I have written about and published in peer reviewed journals and books for roughly the last 25 years. I participated in the creation of the original TCPS through submission of commentaries on drafts. The growing pains associated with the new national policy statement soon led the Presidents of the granting agencies (the official stewards of the TCPS) to create several committees to advise them on improvements. These became so extensive the new version was dubbed TCPS 2.0. I was one of 5 academics from across the country appointed to one of those committees -- the Social Sciences and Humanities Working Committee (SSHWC) on Research Ethics -- and also served as SSHWC's liaison to the committee that developed the guidelines for research involving Indigenous People/s. More recently, I was appointed a member of the editorial board for one of the premiere international journals in the field, the [*Journal of Academic Ethics*](#). I appreciate the opportunity to comment on the proposed revisions to the SFU Ethics Policy R20.01 that will be considered by Senate imminently.

I mention all the above in part to convey that I have been around and an active participant in the formalization of ethical standards in Canada for long enough to appreciate why various developments happened, the faults they were designed to repair, and the impacts of those changes both at SFU and nationally. On the basis of that history, I was pleased to see some of the changes that were incorporated in the SOPs on the basis of feedback from Senate and the Special Joint Committee, but dismayed to find that other aspects of the proposed changes to SFU's ethics policy convey a lack of perspective and showed a misunderstanding of human research ethics and ethics review in several key respects that I believe will undermine our ability to engage in effective ethics review. In that regard, I will refrain from undertaking a detailed inventory of the ways that the 160-page set of procedures that are proposed would impede rather than facilitate ethical research in the social sciences and humanities. The flaws in the proposed changes are more fundamental than that. Accordingly, I will begin with a few comments on changes made by Senate and the Special Joint Committee of the Senate and Board of Governors over the summer and continue with discussion of what for me are the three fundamental problems that remain with the proposals:

- (1) the choice to adopt only the clinical procedures created by the Canadian Association of Research Ethics Boards (CAREB);
- (2) the question of whether the REB membership proposed in SOP 201.004 ("Composition of the REB") is adequate to fulfill the admirable aspirations to promote ethical research through thoughtful and competent ethics review that are outlined in both the former and proposed R20.01; and
- (3) the choice to remain with one ethics review committee for all SFU research involving human participants.

Work Thus Far

I appreciate that Senate encouraged the Special Joint Committee of the Senate and Board of Governors to make changes/edits to the versions of SOPs 201, 202 and 302 that were circulated over the summer. A flaw that characterized many of the earlier proposals from the VPRI was that they appeared to allow rather than avoid institutional conflicts of interest. Accordingly, the recent edits that make clear that legal advisors to the university should have no role in the REB, and that senior administrators should be clearly precluded from being members or acting in any capacity that might undermine REB independence are positive changes that will help ensure the new R20.01 remains consistent with TCPS2. I have residual concerns about the extent to which the Director of Research Ethics – a VPRI appointee – is involved in REB decision-making, but support these to the extent that it appears the Director’s decisions are intended only to advise the REB and its Chair, with final decisions on issues like membership ultimately overseen by the Chair and/or REB.

The Choice to Incorporate Only the Clinical SOPs Created by CAREB

It is telling that the “Explanatory Notes” that preface the lengthy package of SOPs contains this explanation for the choice:

Two sets of SOPs are available: one for ethics boards that review health sciences research (i.e. including clinical trials), and another for behavioural research. Since SFU reviews both types we have adopted the former – as they are more stringent [sic] and assure that SFU will be compliant with both Canadian and US regulatory criteria for all types of research.

The quote portrays a significant misunderstanding of the nature of ethics review and the way that ethics issues play out in different contexts. A brief historical review may help. The first version of the TCPS was released in 1999/2000. As recounted by Dr. Michael McDonald,¹ a bioethicist, former Director of the Centre for Applied Ethics at UBC and one of the authors of the original draft TCPS, the decision to create a TCPS came about in part from “increasing private sector dollars pouring particularly into medical research, much of this in the private sector” and “pressures on REBs to issue quick and favourable verdicts on research proposals” (p2).² Accordingly, the majority of those who authored the first report were bioethicists, medical practitioners and legal scholars, with the result that the first TCPS was heavily influenced by biomedical conceptions of ethics.

Although McDonald suggests in a later paper³ that due consideration was given to creating multiple policies for different research traditions, in the end the choice was made to create a one-size-fits-all policy. It did not take long to determine that was a poor decision. Complaints from researchers in the social sciences and humanities were particularly trenchant, focusing on “ethics creep” and ways the

¹ McDonald, M. (1998). The *Tri-Council Policy Statement* on ethical conduct for research involving humans. *Canadian Bioethics Society Newsletter*, 3(3), 1-2.

² The scandal at the University of Toronto involving Dr. Nancy Olivieri and Apotex, a “Global Health Company,” was a potent illustration of this problem (see <https://www.caut.ca/latest/publications/books/the-olivieri-report>).

³ McDonald, M. (2009). From Code to Policy Statement: Creating Canadian Policy for Ethical Research Involving Humans. *Health Law Review*, 17, 2-3.

initial Policy Statement was actually impeding research by imposing supposedly universal “ethical principles” that would actually make some social science research *unethical* if implemented! While some in the biomedical community expressed the view echoed in the currently proposed SFU Policy that social scientists simply were not used to what were referred to as “more stringent” biomedical standards, further discussion made it clear simply that the medical and behavioural sciences⁴ operate on very different models in very different contexts and, because of that, ethics issues can play out in very different ways, even though many of the foundational principles – consent, confidentiality, avoiding conflicts of interest and conflicts of role, protecting research participants – are the same.

If “being ethical” meant only implementing isolated ethical principles, then ethics would be easy and ethics review a waste of time. The problem is that multiple ethical principles operate simultaneously and sometimes pull in different directions, requiring judicious resolutions that maximize outcomes for participants overall while simultaneously retaining methodological integrity. To give one example, clinical trials involve individuals who willingly expose themselves to risk – and often very high levels of risk -- in order to test out novel drugs and procedures in a highly legally regulated environment. The ethical emphasis in that context is on informed consent, which is rigorously documented in order to meet legal standards, with consent typically requiring a signature signifying that the participant has been informed of the risks and still consents to the drug or procedure. In the social sciences, risks are reduced – we are rarely in the position where our interventions have the potential to kill people -- and are often more easily managed. However, because disclosures of what people tell us or that we find out about in so many areas of human existence can create problems for participants – losing their jobs, being divorced by their partner, feeling humiliated, being incarcerated – the greater emphasis is on maintaining confidentiality so that the knowledge we gain is never at the expense of the participant’s well-being. In that context, what is seen in biomedical contexts as the “more stringent” standard of “signed consent” does nothing but create greater risk for the participant in the social sciences by creating needless paper trails.

Complaints about TCPS1 were voluminous, particularly from those in the social sciences and humanities. It was clear that biomedical approaches to research ethics were very often ill-suited to the social sciences and humanities, and particularly for more qualitative methods. It was time for TCPS 2. The Presidents of the granting agencies created numerous committees commencing in about 2005 to give the TCPS an overhaul with a major emphasis on making the TCPS more compatible with and better reflecting the needs of the social sciences and humanities. Wording throughout TCPS 2 was changed to allow for a more diverse array of methods and approaches, and new chapters were added to guide REBs by explaining the logic underlying research traditions that do not share positivist and biomedical norms. For example, SSHWC drafted Chapter 10 on qualitative research because the way ethical principles play out in more inductive/emergent/collaborative field research contexts can depart significantly from the issues that arise within the more positivistic approaches that were prioritized in the original TCPS. Another committee devoted to research with Indigenous people/s and in Indigenous contexts drafted

⁴ I gloss over for the moment the diversity of approaches found even within the behavioural sciences, which can be as great as the differences between the behavioural and clinical/medical domains.

Chapter 9 because of the unique circumstances of Indigenous Peoples, and the unique requirements and protocols related to Indigenous ways of knowing and participating.

Understanding that history illustrates how the “explanatory notes” that justify the proposed use of use of clinical SOPs because they are “more stringent” than those developed for behavioural research ring hollow and untrue. CAREB, whose roots are actually more in the biomedical field than the social sciences have developed two sets of SOPs for good reason: ethical decision-making in the clinical and behavioural realms run in parallel universes that sometimes require different resolutions in order to ensure that each is “being ethical” and that disciplinary norms are respected in the contexts in which they operate. If SFU is to adopt CAREB’s SOPs, then it should adopt both sets for the respective domains of research.

Can Two Faculty Members Competently Evaluate the Full Diversity of Research at SFU?

Although ethics at SFU has occasionally embraced a rather scandalous past,⁵ the last decade has been relatively calmer, at least until this past summer. I presume that part of the rationale for creating a new R20.01 at this time is because of the commitment that SFU has been made to creating a new medical school. A fundamental requirement of quality ethics review is that it be done by people who have the appropriate expertise to do so. The structure proposed in SOP 201.004 is to have one REB constructed as follows:

5.2.3 The REB will include at least **seven voting** members represented by the following categories:

- At least two **SFU faculty** members who have expertise in relevant research disciplines, field and methodologies covered by the REB (for biomedical clinical trials, this will include at least one member who practises medicine or dentistry and who is in good standing with their regulatory body),
- At least one member who is primarily experienced in non-scientific disciplines
- At least one member who is knowledgeable in ethics,
- At least one member who is knowledgeable in the relevant law **and is not the institution’s legal counsel or risk manager**. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research,
- At least one community member who has no affiliation with the **University** or the sponsor, and who is not part of the immediate family of a person who is affiliated with the **University**, **and**
- **At least one member who is a graduate student of the University;**

One can only speculate who the two faculty members might be in a large and soon to be larger institution like SFU who will feel competent evaluating a clinical trial for a new drug, a laboratory experiment in social psychology that involves deceiving participants, a discourse analysis in criminology that examines claims made by right wing extremists , a medical treatment designed to alleviate the pain of gonorrhoea, an educational intervention to teach elementary school children about their bodies, and a communications researcher examining the way Indigenous land protectors are using social media to develop strategies to evade arrest and assert their People’s land rights. Although I pride myself in a

⁵ See, for example, T. Palys & J. Lowman (2014). *Protecting Research Confidentiality: What Happens When Law and Ethics Collide*. (Published as part of CAUT’s Academic Freedom series.) Toronto: Lorimer.

certain breadth of knowledge and interests, it certainly won't be me, and frankly, I would worry about anyone who thinks it might be them. It is critical that people making decisions or performing reviews have the requisite knowledge and experience to understand both the risks and the potential benefits of any proposed project.

Although I will question below the choice to remain with one REB, at the very least SFU should be entertaining the possibility of creating a larger committee reflecting the diversity in research areas and approaches that exists and will continue to grow at SFU. Doing so would be fully consistent with TCPS Article 6.4, whose explanatory notes state,

The size of an REB may vary based on the diversity of disciplines, fields of research and methodologies to be covered by the REB, as well as on the needs of the institution. In appointing REB members, institutions should strive for appropriate diversity. Institutions may need to exceed the minimum REB membership requirements to ensure adequate and thorough reviews as well as reasonable workload for REB members, or to respond to other local, provincial/territorial, or federal legal or regulatory requirements.

Most problematic these days at SFU from what I have seen is the lack of attention given to Indigenous research that attempts to remain true to Indigenous knowledge production and sharing protocols. The academy has progressed to encouraging respectful relations when settler researchers engage Indigenous communities, but has been slow to articulate principles based on research now done with and by Indigenous people/s rather than on them. Methods that none of the rest of us learned in grad school challenge the relevance of existing guidelines. For example, my colleague annie ross, a Professor in the Department of Indigenous Studies, has for years been attempting to find a reasonable way to engage the Office of Research Ethics regarding her method of choice – *testimonio* -- which is based in the right of Indigenous and other Peoples to bear witness about their (usually marginalized) experience. We all know methods that *testimonio* is somewhat like – oral history, qualitative interviewing, participatory action research – but to evaluate my colleague's proposals on the basis of what it is *like* rather than what it *is* does an injustice to the method and is a very colonial thing to do. Indigenous scholars and others interested in Indigenous issues deserve better than the token representation currently envisioned by the proposed policy and procedures.

Does SFU Need More Than One REB?

The discussion above has highlighted the inadequacy and potential problems that would arise by imposing clinical SOPs on all research because of the different ways that ethics principles are addressed within different research approaches, disciplines and areas of inquiry. When we add in the requirement that REBs include a membership that is competent to review the full range of research it is asked to evaluate, surely SFU would be far better served by creating at least two REBs once the medical school is established. Doing so would be consistent with the TCPS, which states in the explanation to Article 6.1 that,

The number of REBs and the expertise of their members will depend on the range and volume of research for which that institution is responsible, in accordance with [Articles 6.4](#) and [6.5](#) relating

to REB composition. Large institutions may find it necessary to create more than one REB to cover different areas of research or to accommodate a large volume of research.

In that regard, we can look to other universities for the ethics review structures they have created. In the search for appropriate role models, I went to the Times Higher Education list of World Rankings⁶ to identify all Canadian universities that are ranked more highly than SFU. There are 11 Canadian universities above us in that list, all of which have medical schools associated with them. Appendix A shows the eleven, along with a brief indication of the number and type of REBs each has created. It is noteworthy that every single one of them has at least two REBs – one for behavioural and another for clinical research – with some institutions having as many as four and one with five. Two would seem the minimum for any institution that has a medical school and is serious about providing epistemologically sensitive and ethically competent review.

In Closing

SFU has achieved much in its almost 60 years of existence as a “medium” size institution – consistently ranking in the top three and often at the top of the list of medium-sized universities -- and now prepares to make the jump to the elite group of large universities that house medical schools in addition to the broad array of research that characterizes any contemporary university. But if SFU seriously wants to join the big leagues, then it should behave in big league fashion with respect to ethics. Doing so, in my view, would mean

- (a) engaging processes of collegial governance that would see SFU go back to Square 1 at this potentially significant turning point in its institutional history to commence a broad process of consultation before the med school is upon us about the sorts of revisions to R20.01 that would benefit a socially responsive and responsible institution’s ethics policy;
- (b) revisiting the question of how many REBs and what form they should take in order to best balance appropriate ethical scrutiny with efficiency of review that does not infringe academic freedom;
- (c) showing national leadership on some issue of national importance. My nomination would be for SFU to establish the first REB devoted specifically to research involving Indigenous People/s, better serving those at SFU who do such research, establishing them as more of a community, and developing practices/processes that potentially would become a model for other institutions about how research by/with/for Indigenous Peoples should be reviewed in a respectful manner that ensures both its ethical probity and methodological and cultural integrity.

⁶ See <https://www.timeshighereducation.com/world-university-rankings>

Appendix A

Number and Types of Ethics Review Committees Created by the Eleven Canadian Universities Ranked More Highly than SFU According to the Times Higher Education (THE) World Rankings for 2023

THE Rank	University	Number and Types of REBs
18	University of Toronto	<p>(1) Health Sciences REB reviews research from Medicine, Applied Science & Engineering, Nursing, Pharmaceutical Sciences, Social Work, Physical Education & Health, Dentistry, School of Public Health</p> <p>(2) Social Sciences, Humanities and Education REB reviews research from Arts & Science, Information, Music, Education, and School of Theology</p>
40	University of British Columbia	<p>(1) Behavioural REB reviews projects that involve people interacting with their surroundings, including each other, their communities and institutional systems</p> <p>(2) Clinical REB reviews research that evaluates the effects of health-related interventions on health outcomes, e.g., drugs, surgical procedures, devices, genetic therapies.</p>
46	McGill University	<p>(1) REB1 = Law, Management, Art, Engineering, Science, Agricultural and Environmental Sciences;</p> <p>(2) REB2 = Education, Music, Linguistics, Psychology, Social Work, Information Studies, Nutrition, Food Sciences;</p> <p>(3) REB3 = Research involving minors and adults incapable of giving consent;</p> <p>(4) REB4 = Faculty of Medicine REB for research involving medical procedures or interventions, genetic testing, medical imaging, use of biological materials</p>
85	McMaster University	<p>(1) Hamilton Integrated REB reviews research from Faculty of Health Sciences, Hamilton Health Sciences, St. Joseph's Healthcare and Niagara Health</p> <p>(2) McMaster REB reviews all other research from Faculties of Science, Social Sciences, Humanities, Engineering and Business</p>
111	Université de Montréal	<p>(1) Comité d'éthique de la recherche en arts et humanités</p> <p>(2) Comité d'éthique de la recherche – Société et culture</p> <p>(3) Comité d'éthique de la recherche en éducation et en psychologie</p> <p>(4) Comité d'éthique de la recherche clinique</p> <p>(5) Comité d'éthique de la recherche en sciences et en santé</p>

118	University of Alberta	<p>(1) REB1 and REB2 review social sciences, behavioral, education, arts, business, humanities, and engineering research conducted by University staff and students</p> <p>(2) The Health Research Ethics Board (HREB) includes the former Capital Health (now AHS), Caritas Health (now Covenant Health) and the University of Alberta. HREB operates as two panels (REB 3 - HREB Health Panel and REB 4 - HREB Biomedical Panel) and reviews research involving health information, chart reviews, population health studies, clinical interventions and clinical trials.</p>
137	University of Ottawa	<p>(1) Social sciences and Humanities REB evaluates all research projects originating from School of Management and the Faculties of Arts, Education, Law and Social Sciences (except Psychology)</p> <p>(2) Health Sciences and Science REB evaluates all projects from the Faculties of Engineering, Science, Health Sciences, Medicine and Psychology</p>
201-250	University of Calgary	<p>(1) Conjoint Faculties REB reviews applications from researchers from Arts, Education, Engineering, Environmental Design, Business, Law, Science, Social Work, Veterinary Medicine and Libraries and Cultural Resources</p> <p>(2) Conjoint Health REB reviews applications from Kinesiology, Medicine and Nursing.</p>
201-250	University of Waterloo	<p>(1) Clinical REB for medical interventions that pose greater than minimal risk</p> <p>(2) Human REB for other human research that poses greater than minimal risk to participants</p> <p>(3) A third process for minimal risk projects allows such proposals to be reviewed by a Delegated Ethics Review Committee comprised of faculty members within a department</p>
201-250	Western University	<p>(1) Health Sciences REB reviews studies in clinical settings and those involving physical interventions or procedures</p> <p>(2) A Non-Medical REB reviews social, behavioural, cultural and humanities research</p>
251-300	Queen's University	<p>(1) Health Sciences and Affiliated Hospitals REB reviews research involving any research in health care settings, or involving pharmaceutical devices or drugs, medical or physical interventions, new medical techniques, medical or dental patients, biological materials, health or medical records, medical tests, and biobanks</p> <p>(2) General REB reviews all other research</p>
251-300	Simon Fraser University	<p>(1) One REB for all research involving human participants</p>