



T.S. Palys, Ph.D.
FACULTY OF ARTS AND SOCIAL SCIENCES
Professor, School of Criminology
Associate Member, Dept. of Indigenous Studies

Saywell Hall
8888 University Drive,
Burnaby, BC
Canada V5A 1S6

TEL
778.782.3213

palys@sfu.ca
<http://www.sfu.ca/~palys/>

26 February 2023

Karen Wallace
Executive Director
Secretariat on Responsible Conduct of Research (SRCR)
Ottawa, Ontario K1A 0W9

Sent via email to secretariat@srcr-scrs.gc.ca

Ms. Wallace:

The purpose of this letter is to lodge a formal complaint about and to seek your intervention regarding violations of *Tri-Council Policy Statement 2.0* (TCPS2) by Simon Fraser University's administration, specifically its violations of TCPS2 provisions regarding institutional conflict of interest by recent actions and proposals by its Vice-President of Research & International (VPRI).

Simon Fraser University currently has an [ethics policy \(R20.01\)](#) that, in accordance with its MOUs with the three federal granting councils (SSHRC, NSERC and CIHR), is consistent with the TCPS provisions regarding institutional conflict of interest.

TCPS2 defines institutional conflict of interest and outlines in **Chapter 7** the problems that can arise when institutional conflicts of interest are not held in check:

An institutional conflict of interest involves a conflict between at least two substantial institutional obligations that cannot be adequately fulfilled without compromising one or both obligations. Conflicts may occur when pursuing particular goals, for instance, the pursuit of two different "goods," such as an effort to obtain general infrastructure funding from a donor that conflicts with an effort to promote research that the donor does not wish to support.

Institutional conflicts of interest may compromise duties of loyalty and lead to biased judgments. Conflicts may also undermine public trust in the ability of the institution to carry out its missions, operations, and ethical responsibilities in research. (p.125)

TCPS2 also outlines in Chapter 6 some of the many policy requirements that ensure institutions do not violate its institutional conflict of interest provisions. In particular, I note the following:

Article 6.1 requires institutions to establish Research Ethics Boards:

Institutions shall establish or appoint an REB (or REBs) to review the ethical acceptability of all research involving humans conducted within their jurisdiction or under their

auspices, that is, by their faculty, staff or students, regardless of where the research is conducted, in accordance with this Policy (p.93)

Article 6.2 requires these to be established by “the highest body within an institution” and adds that REBs must be independent in their decision-making and accountable to that “highest body:”

The highest body within an institution shall: establish the REB or REBs; define an appropriate reporting relationship with the REBs; and ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties. REBs are independent in their decision making and are accountable to the highest body that established them for the process of research ethics review. (p.95)

Article 6.3 affirms that the power to review and then to approve or reject proposals lies with the REB:

The institution shall grant the REB the mandate to review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. This mandate shall apply to research conducted under the auspices or within the jurisdiction of the institution, using the considerations set forth in this Policy. (p.96)

Article 6.4 outlines the minimum requirements for an REB’s membership, and, under “application,” encourages the REB to develop “strong relationships” with the host institution and its senior administration and any administrative staff whose job is to “support” REB procedures. However, the “application” section goes on to remind readers that those relationships must not cross lines that violate REB independence:

However, an institutional senior administrator (e.g., vice- president of research, director general or director of business development) should not serve on an REB, or directly or indirectly influence the REB decision-making process (p.98)

Article 6.5 acknowledges that relevant expertise may not always exist on the committee, and thereby allows the REB the capability to identify and consult ad hoc advisors to aid its review of particular proposals:

The REB should have provisions for consulting ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. (p.100)

Article 6.8 acknowledges the special role of the REB Chair:

The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of this Policy. (p.102)

After formal adoption of the TCPS by the granting agencies in 1998, SFU initiated a broadly consultative process designed to establish an ethics policy consistent with the principles outlined in the TCPS as a prerequisite for being able to access federal grant funds, and signed MOUs with SSHRC, NSERC and CIHR to that effect.

Although the TCPS recognizes that various bodies within an institution might be identified as its “highest body” because of the diversity of institutions that might wish to access federal grant funds (p.95), at

SFU, as with most universities, the admonition to avoid institutional conflicts of interest was accomplished by having the ethics policy identify the University's Senate as its "highest body in the institution." Senate would then proceed to create an ethics policy (R20.01) that echoed TCPS provisions in **Articles 6.2, 6.3 and 6.4** regarding the avoidance of institutional conflict of interest. In particular,

- (1) the REB would be independent of administrative influence, including the appointment of members and choice of Chair;
- (2) asserting specifically in the policy that, "The REB shall operate in an impartial manner and be independent in its decision making," and further that, "The decisions of the REB are not subject to review or interference by the Vice-President, Research and International, the Senate, or any other person or body[.]" ; and
- (3) allowing initial review of minimal risk proposals to be delegated to a newly created Office of Research Ethics (ORE), but whose decisions would not become 'final' until they were reviewed by the REB.

These elements have served SFU until recently, when some actions and proposals by the current Vice-President of Research & International (VPRI), Dr. Dugan O'Neil, have re-created the very institutional conflicts of interest those safeguards were intended to avoid, and which have led me to lodge this formal complaint. More specifically, the VPRI's initiatives have created four major problems that fall into two general categories.

The first general problem lies with the issue of administrative interference in REB membership and decision-making:

- (1) the university's Vice President of Research and International (VPRI) has violated the institutional conflict of interest provisions of the TCPS by unilaterally terminating some REB members, including its Chair and Vice-Chair;
- (2) by virtue of the terminations described in (1), the university no longer has a functioning REB that meets the minimum requirements of either the TCPS or SFU's existing ethics policy (R20.01);

The above are particularly problematic because they represent situations where the VPRI has already acted on his institutional conflict of interest and created a violation of the TCPS that the SFU administration has shown little sign of attempting to resolve in a manner that is compliant with the TCPS.

The second general problem lies with changes to the ethics policy that the VPRI has introduced which create further violations of TCPS provisions regarding institutional conflict of interest. By way of general summary,

- (3) the university's VPRI proposed changes to the review process that violate TCPS provisions regarding institutional conflict of interest and REB independence by placing ethics review within the VPRI's office without REB oversight, allowing him to choose which "experts" will be consulted on contentious proposals, and giving himself and his staff the power to appoint and terminate REB members; and
- (4) because Senate did not immediately rectify the VPRI's violation of TCPS provisions regarding institutional conflict of interest and REB independence by reinstating the REB members, leaving SFU without an REB that is consistent with TCPS requirements, what began as the VPRI's "proposals" have become the *de facto* ethics policy, thereby violating TCPS provisions regarding institutional conflict of interest and the need for REB independence.

I elaborate on each of these below.

1. The VPRI Terminates REB Members

When members of the REB returned to the university in January after the winter holiday break, they were greeted with a letter informing them that the VPRI had decided to create and implement various changes to the SFU ethics review process. That letter was followed by others to four members of the REB – its Chair, Vice-Chair, and two other committee members – thanking them for their service while informing them that they were being terminated, effective immediately.

- (a) These actions by the VPRI violate **TCPS Article 6.2**, which affirms that it is only “the highest body within an institution” that can establish the REB or REBs. At SFU, that body has been designated as Senate.
- (b) By intervening directly in REB membership, the VPRI also has violated **Article 6.2’s** admonition regarding the need for REB independence and its accountability to SFU’s “highest body” – Senate.
- (c) The VPRI’s actions further undermine REB independence by violating **TCPS Article 6.4**, which affirms that university administrators must not “directly or indirectly” influence REB decision-making. His abrupt termination of four members creates a chill by showing remaining members their continued presence is dependent on his discretion instead of Senate.

2. SFU No Longer Has an REB that Complies With the TCPS

By terminating the Chair, Vice-Chair and two members, the VPRI has left the committee with a group that does not meet the membership requirements of the TCPS. In doing so, SFU is now in violation of the requirement in **TCPS Article 6.1** that, “The institution shall establish or appoint an REB (or REBs) ... in accordance with this policy.” While Senate had an opportunity to rectify the VPRI’s violation of policy by reinstating the members who were terminated at a meeting on February 6 where the ethics policy was discussed, it failed to do so.

A particularly problematic aspect of the VPRI’s actions is that, by terminating both the REB’s Chair and Vice-Chair, the REB was left without the authority that **TCPS Article 6.8** vests in the Chair for overall oversight regarding SFU’s compliance with the policy. It is noteworthy that the former Chair, Wendy Loken Thornton, had requested the opportunity to speak at Senate’s February 6 meeting where the ethics policy and the VPRI’s actions were to be discussed, but was refused permission to do so.

It is also noteworthy here that, consistent with **Articles 6.2 and 6.3 of the TCPS, Section 1.5.1 Schedule A** of the SFU Ethics Policy requires that “The Chair of the REB ... will be elected by the current board members,” and that “At least one Deputy Chair will be appointed by election.” The VPRI’s termination of both the Chair and Vice-Chair violates that requirement by usurping the Board’s discretion in that regard and is another example of the VPRI violating the TCPS requirement to ensure REB independence and avoid institutional conflicts of interest.

3. The VPRI Informs Senate of His Changes to Policy

The VPRI has proposed changes to the SFU ethics policy that he characterized as mere “procedural changes” that did not require Senate approval, but that is clearly is not the case. “Procedural” changes would be within the authority of the VPRI to change without violating either the TCPS or SFU Ethics Policy requirements, although for the purposes of this complaint I will focus on how his proposals – some of which are already being enacted (see #4 below) – violate provisions for REB independence and institutional conflict of interest required by the TCPS.

In articulating this section, I pay particular heed to the TCPS articulation of institutional conflicts of interest, and particularly the TCPS example of the types of arrangements that would violate its provisions:

Institutions may be in conflict of interest, for example, when they ... d) have conflicting roles carried out by one institutional official (e.g., a vice-president who is responsible for the promotion of research activity and funding and also for oversight of research). (p.125)

In general terms, the VPRI gives a contemporary face to the very example that the TCPS uses to illustrate institutional conflict of interest, going well beyond any mere “perception” of conflict of interest to actually creating it. More specifically, the VPRI’s proposals violate the TCPS by shifting the locus of decision-making authority regarding key review processes and determination of membership from the REB to the VPRI and the Director of Research Ethics (DORE), whom he appoints, thereby violating TCPS provisions regarding REB independence and the avoidance of institutional conflict of interest. I will focus on his proposals documented in *SOP 202 – Management of REB Membership*. Problematic aspects of his proposals include the following:

- (a) Section 3.0 regarding “Responsibilities” asserts that, “The management of the membership of the REB and oversight of member appointments, REB related activities, communications, and other administrative details are the responsibility of the Director, Research Ethics.” By moving oversight regarding member appointments from the REB to the DORE, a VPRI appointee, the VPRI’s proposals undermine REB independence and violate TCPS provisions regarding institutional conflict of interest. Of particular concern here is also that the ambiguity of terms like “other administrative details” and “REB related activities” might allow the VPRI to exert control over review of “minimal risk” proposals, which currently are done by ORE, but with REB oversight to avoid opportunities for institutional conflicts of interest. To leave that responsibility completely within the ORE would create the opportunity for institutional conflicts of interest to intrude by manipulation of the way applications are categorized.
- (b) Section 5.2 regarding “Appointments – Regular Members and Alternates,” includes the following provisions:
 - a. 5.2.1 The Vice-President, Research and International (VPRI) or designee has the authority to appoint members to the REB.
 - b. 5.2.2 The VPRI delegates recruitment, selection and vetting of REB members to the Director, Research Ethics.
 - c. 5.2.5 Each REB member selected is appointed by the VPRI or designee;

By usurping Senate’s role in appointing members to the REB and giving his office that responsibility, the VPRI creates a perception of institutional conflict of interest by giving his office the opportunity to manipulate REB membership according to administrative priorities that may conflict with ethical responsibilities.

- (c) Section 5.3 regarding “Appointments – REB Chair and Vice-Chair,” the VPRI’s proposals include the following:
 - a. 5.3.1 The REB Chair and Vice-Chair (if applicable) are appointed by the VPRI or designee.
 - b. 5.3.2 The REB Chair and Vice-Chair (if applicable) are recruited, selected and vetted by the Director, Research Ethics.

By directly intervening in the choice of REB Chair and Vice-Chair, these proposals violate REB independence (current policy leaves this responsibility with the REB) and create the

perception of institutional conflict of interest by giving the VPRI's office the power to choose Chairs and Vice-Chairs who reflect administrative priorities.

(d) Section 5.4 regarding "Ad hoc Advisors," includes the following:

- a. 5.4.1 At their discretion, the Director, Research Ethics may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the REB.

By locating the identification and appointment of ad hoc advisors within the VPRI's office, the proposal violates REB independence in the identification of experts and creates the problem that institutional conflicts of interest may create bias in the choice of experts .

(e) Section 5.5. on "Terms of Appointment" include the following provisions:

- a. 5.5.2 Renewal of appointment may occur for a term of two or three years, by mutual agreement of the VPRI or designee, Director Research Ethics, REB Chair and REB member. An additional two or three-year renewal period may be granted upon mutual agreement. Every effort will be made to ensure continuity and a core of knowledgeable and experienced members.
- b. 5.5.3 The REB Chair and Vice-Chair (if applicable) will be appointed by the VPRI or designee and shall serve, initially, for a term of one year, renewable and at the discretion of the VPRI or designee and with the agreement of the individual serving, for an additional two years. At the expiry of the initial three-year term, the appointment may be renewable for a single additional term at the discretion of VPRI or designee and with the agreement of the individual serving.

These sections violate TCPS provisions regarding institutional conflicts of interest by giving the VPRI veto power in the appointment of members (5.5.2), thereby usurping Senate's role in the appointment of REB Members. By giving his office the power to choose and renew the REB's Chair and Vice-Chair (5.5.3), the VPRI violates TCPS provisions regarding institutional conflict of interest, and creates a potentially chilling effect on REB independence.

(f) The VPRI's infringement of REB independence continues in Section 5.7.4 of his proposals:

- a. Members who are not compliant with 5.7.2 and 5.7.3, other than the REB Chair, may be removed at the discretion of the REB Chair or the VPRI or designee, following consultation with the Director, Research Ethics, or in the case of a member who is the REB Chair, by the Director, Research Ethics in consultation with the VPRI or designee;

By allowing the VPRI to remove members he deems non-compliant, requiring him only to "consult" with the REB before doing so, the VPRI's proposals usurp the power of Senate and create the opportunity for institutional prerogatives to enter the decision-making process.

4. The VPRI's Proposals Have Become *De Facto* Policy

The VPRI's changes to policy were introduced at a meeting of Senate on 6 February 2023. The outcome of that meeting was mixed. On the one hand, Senate appropriately did *not* accept the VPRI's proposals, and instead sent them to a Senate Subcommittee – the Senate Committee on Agenda and Rules – "to ensure compliance with national standards." On the other hand, Senate failed to acknowledge the violation of the TCPS provisions regarding REB independence and institutional conflicts of interest that were involved in the VPRI's termination of the REB Chair, Vice-Chair and two other members. By failing simply to acknowledge the VPRI's violation and reinstate the terminated members, the result is that we no longer have an REB, and thus no body to oversee the recruitment process, which, according to SFU

policy, is supposed to be done by ORE with REB oversight to ensure REB independence and avoid institutional conflicts of interest created by the VPRI's involvement. Furthermore, without an REB as the TCPS requires, any consideration of proposals of even "minimal risk" proposals by VPRI staff violates the TCPS by precluding REB oversight.

The Senate Committee on Agenda and Rules (SCAR) to whom this situation was referred, more recently attempted to patch together a solution that does little more than take the administration's violations of the TCPS a step further. The VPRI's proposals for *SOP 202 – Management of REB Membership* now includes the following notice:

This SOP is currently under review by a joint Senate – Board of Governors committee (Joint Committee). While the Joint Committee is operating, the role of the VPRI in 5.2.1, 5.3.1, 5.5.3 and 5.7.4 (appointments and removals) will be assumed by a committee comprised of the Director of ORE, a member of the REB, and one other independent faculty member appointed by the President. Further, in the interim the Chair of the REB will be appointed by the president, in consultation with this same committee.

It is noteworthy the three-member committee SCAR created is dominated by administration appointees – the Director of ORE (appointed by the VPRI), and an "independent" faculty member appointed by the President. There is no indication of how "independence" is to be established, nor is there any mention of how or by whom the "REB member" might be chosen. Because the Chair and Vice-Chair were already terminated by the VPRI, the obvious choice of REB Member – its Chair – is unable to advise on the process. This violates **TCPS Article 7.2**, which states that,

Institutions should ensure that real, potential or perceived institutional conflicts of interest that may affect research are reported to the REB through established conflict of interest mechanisms. The REB shall consider whether the institutional conflict of interest should be disclosed to prospective participants as part of the consent process. (p.128)

Added to this problem is SCAR's decision to allow the President to appoint a new Chair. Can there be a more obvious institutional conflict of interest than the President appointing a Chair who will make decisions about whether the VPRI's proposals and the President's involvement in this process violate the TCPS? Even if this step were not taken, how ironic that the institutional authority for determining conflicts of interest and conflicts of commitment when research participants are potentially affected is the very same REB the VPRI has just dismantled by his termination of the Chair, Vice-Chair and two other members.

In Conclusion

According to Michael McDonald, former Director of the W. Maurice Young Centre for Applied Ethics at UBC, recipient of a Canadian Bioethics Society Lifetime Achievement Award, now Professor Emeritus and one of the authors of the early drafts of what became TCPS1, the development of the national standards embodied in the TCPS became necessary as a counter-balance to growing concern regarding "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."¹

How coincidental that the VPRI's efforts to seize control of ethics review processes come at exactly the time SFU has announced its intention to go from being a mid-size university to joining the Big Leagues by creating a medical school. If they haven't already, one can imagine multinational pharmaceutical

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

companies will soon be calling, offering tens of millions for a new building and partnerships for prospective drug patents. This is exactly the time when SFU should be re-examining its ethics and conflict of interest policies to anticipate the changes that inevitably will come with a medical facility and medical research that will bring with it huge potential for institutional conflicts of interest.

It is over concern for that future that I submit this complaint against the university and request your intervention. In my view, this would entail

- (1) a statement that the formerly functioning REB should be reinstated to rectify the VPRI's violation of both the TCPS and SFU ethics policy's provisions regarding institutional conflicts of interest; and
- (2) rulings on whether the portions of the VPRI's proposals I have detailed above do indeed violate the TCPS.

Research participants and our diverse research community deserve policy and procedure that are consistent with the TCPS, and SFU should be reminded that its continuing access to federal research funding is at risk of being held in abeyance until that is the case.

Sincerely,

Original signed by
Ted Palys, PhD
Professor, School of Criminology
Associate Member, Dept. of Indigenous Studies