

Re : Information item - Procedure Changes (R20.01)

To : SFU Senate

Summary:

The VPRI is poised to implement a series of procedure changes associated with policy R20.01 (Ethics Review of Research Involving Human Participants). While procedural changes do not require approval of Senate, the planned changes are significant and are being flagged for Senate for the sake of transparency and community awareness.

The planned procedural changes are intended to align SFU ethics processes with other institutions in BC and Canada. They include a wholesale switch to the standard operating procedures (SOPs) created by the Canadian Association of Research Ethics Boards (CAREB), edited as required for our local needs. The CAREB SOPs are designed to be compliant with both Canadian and US regulations, including clinical research and clinical trials. The SFU draft SOPs are available for review (<https://www.sfu.ca/research/researcher-resources/ethics-human-research/standard-operating-procedures>) as are the national standard SOPs (<https://careb-accor.org/resources-section/n2-careb-accor-reb-sops/>), and the existing SFU procedures linked from the bottom of the R20.01 policy page (<http://www.sfu.ca/policies/gazette/research/r20-01.html>).

Additional Context:

Like the other SFU “R20” policies (Biosafety, Treatment of Animals in Research and Teaching, Radiation Safety), Ethics Review of Research Involving Human Participants (R20.01) is subject to external regulation. In the case of R20.01, the Tri-Council Policy Statement 2 (TCPS2) provides a set of national regulations that are updated regularly. As an institution, we have signed an agreement that makes our federal funding contingent on following the TCPS2 standard. The TCPS2 regulations trump SFU policy – in other words, if a researcher is found to have violated TCPS2 they can be federally sanctioned, even if no violation of SFU policy has occurred. Careful alignment of SFU policy with TCPS2 rules and principles is therefore critical for R20.01 and its associated procedures.

The CAREB SOPs are part of a growing nationwide effort to streamline procedures for ethics review in order to make research collaborations involving different universities and health institutions easier for researchers. I, along with other Canadian VPRs, received a letter from the Tri-Agency presidents on January 11, 2023. In addition to addressing the multi-jurisdictional review issues, the letter encouraged Canadian institutions to set and communicate standards for processing times, establish

means for open communication between researchers, and make other changes needed to improve standards and share best practices between institutions.

Roles and Responsibilities:

In 2021, the VPRI office commissioned an external review of our research ethics processes by a panel that included an REB chair and two directors of research ethics offices, together representing three other Canadian institutions. In addition to recommending that we explore adoption of the CAREB SOPs, they noted that “there appears to be a lack of understanding of the roles and responsibilities of the REB and ORE by some SFU stakeholders”. The confusion in the community extends to the roles and responsibilities of the VPRI. The new SOPs help clarify these roles. This clarification has caused some concern in the SFU community – in particular around appointment of REB members.

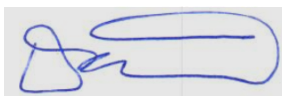
In the new SOPs, the responsibility of VPRI includes appointment of REB members, as well as the chair and deputy chair of the REB. Recruitment and vetting are delegated to the Director, Research Ethics. This VPRI responsibility is aligned with procedures at virtually all large research institutions in the country, including UBC and UVIC. It is also aligned with the other SFU regulatory policies (i.e., the other R20s). A key principle of TCPS2 is that the REB members be vetted and appointed based on their qualifications and training. This is not consistent with a simple open nomination process requiring one representative per Faculty (for example) that might result in positions being filled via acclamation. However, unlike our sister institutions in BC, we have inserted Senate ratification of the REB membership into our SOPs - after appointment by the VPRI.

Under TCPS2 the VPRI is prohibited from serving on the REB or from interfering with any REB decision. The VPRI is also not an appeal route for researchers who dispute an REB decision.

Conclusions:

We are restructuring our research ethics procedures based on advice from our most recent external review, guidance of our regulator, support of the Canadian Association of Research Ethics Boards, and experience with our current processes. The intent is to continue to ensure the safety of human subjects while raising the standard of service to researchers at SFU and fostering interoperability across institutions and jurisdictions.

Sincerely,



Dugan O'Neil (VPRI)