

Letters to the editor

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Excluding individuals who use substances from research: Considerations

Substance use, including the use of illicit drugs and alcohol, continues to be prevalent in our communities, with toxic drug use as the leading cause of death in British Columbia for those who are 10 to 59 years of age.¹ While valid methodological reasons exist for excluding individuals who use substances from research, including concerns about drug–drug interactions or increased medical risks, the rationale for exclusions should be explicit and supported with sound scientific reasoning for research ethics boards (REBs) to consider. Without thorough evaluation, people who use substances may be excluded due to unconscious biases that contribute to stigma.

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)* requires researchers to avoid unjustified exclusions.² Such exclusions diminish sample representativeness, compromise reproducibility, and restrict the development of effective interventions, putting these populations at risk of becoming therapeutic orphans.³ Yet, REBs continue to see clinical research studies exclude individuals who use substances without clear justification, and few resources exist to guide REBs in their appropriate inclusion.

To understand the practice of REBs excluding people who use substances, we conducted an online survey among REB members across BC. The study was approved by the University of British Columbia's Behavioural REB. The results demonstrate the need to support REBs in navigating the complex issue of exclusion,

such as through the implementation of a standardized provincial tool.

Survey responses show that most respondents have reviewed studies with an exclusion for people using illicit substances and alcohol. However, only half were confident in their REB's awareness of their own biases toward this population. When asked about the presence of specific anti-stigma/harm reduction policies, about half confirmed their institution had policies geared toward the inclusion of people who use substances, while the remainder reported it did not or provided no response to this question.

In 2019, estimates showed that 4.6% of BC respondents reported using illicit drugs and 77.2% reported using alcohol within the past year.⁴ Therefore, we invite researchers to consider how they will deal with those who disclose substance use to the study team and to account for individuals who, despite using substances, may choose not to disclose due to stigma or other concerns.

The Interior Health Authority created the Research Applications Checklist for Exclusion Criteria in response to the survey results; it represents a step toward fostering reflection, encouraging discussion, and supporting anti-stigma efforts in health care that can be readily adopted by REBs. To receive a copy of this tool, please contact Dr Silvina Mema (Silvina.Mema@interiorhealth.ca).

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