## Excellent health and care for everyone, everywhere, every time.



## Case Reports and Research Ethics Review at Island Health

Individual patient case reports may not meet the definition of research, depending upon the intent of the report. Individual (single) or at most, two case reports may be considered a medical/educational activity, with no research intent, provided that they are not generalizable beyond the one or two incidents. This is because they do not meet the definition of <u>research</u> in the TCPS2<sup>1</sup>, "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation".

Research Ethics Board (REB) staff should be contacted for a consultation and discussion if you are planning to conduct a case report, and prior to beginning. Note, we do not provide retroactive exemptions or approvals. When contacting REB staff please include the following information:

- Names of authors<sup>2</sup>;
- Title of report to be published;
- Brief summary of report;
- Agreement to obtain consent, or justification for why consent is not possible;
- Confirm no identifiable data will leave Island Health; and,
- Explain how data will be safeguarded.

If the journal to which to plan to publish requires a letter of exemption from ethical review,. Please include this request with your email.

Island Health REBs expect that patients will be made aware that the author/investigator plans to create a report about their case which may be published. Ideally a written consent to publish will be obtained. Case reports for REB purposes are a retrospective analysis of one or two clinical cases. If more than two cases are involved in the analytical activity, the activity will normally constitute "research" and be subject to ethics review.

This does not imply that there are no ethical issues, as there are confidentiality and privacy matters that need to be addressed. There should be a process in place to ensure that the patient is aware that you plan to publish a report about their case, and consent should be sought. Templates are available for consent and/or assent to publish. If recording such as photography or video may be used, that should be made clear as well, including if the image(s) could lead to identification of the individual.

Consent may also be verbal and documented in the medical records, as applicable.

For more information regarding exemption from ethical review, and if you are conducting a quality improvement (QI), assessment or program evaluation, please refer to this <u>page</u>.

<sup>&</sup>lt;sup>1</sup> Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans, December 2022. <a href="https://ethics.gc.ca/eng/policy-politique">https://ethics.gc.ca/eng/policy-politique</a> tcps2-eptc2 2022.html. Retrieved on 2022 March 2.

<sup>&</sup>lt;sup>2</sup> If the authors are from multiple institutions, the case report exemption of review letter can be managed by one REB, via harmonized review with the other institutions' REBs. For questions about this, please consult with REB staff.