

Case Studies at BC Cancer

Case Studies that fall within the following parameters are exempt from REB review:

Generally, case studies do not require REB approval as they do not fall within the definition of research as described in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2.

Specifically, case reports involving three or fewer participants will be exempt from REB review per TCPS 2, Chapter 2 as research is ‘defined as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.’ Case reports usually are unique accounts of individual cases noted during regular practice. These reports are not initiated as inquiry/investigation, nor are they meant to be generalizable.

Key Considerations:

1. Three or fewer participants are involved;
2. The case report(s) cannot be used to answer a research question. There can be no intent to conduct research, answer a research question/hypothesis from the outset of case report;
3. Results cannot be generalized, and no statistical analysis should be performed;
4. Identifiable information and personal information/Personal Health Information (PHI) being used is VERY limited (e.g., age, gender) and coded (i.e. Use partial date of birth/date of death). Information must be coded to ensure individuals cannot be easily re-identified when used in combination.
5. Consent from the individuals to whom the information is derived must be considered. This can be verbal consent but should be documented.
6. There should be no intention to test various therapies/treatments/interventions prospectively or retrospectively.

Case reports not meeting the above criteria should be considered for REB approval. For further information or if in doubt about a specific project, please contact the BC Cancer Research Ethics Office (reb@bccancer.bc.ca).

References

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri- Council Policy Statement: Ethical Conduct for Research Involving Humans*, December 2022.

Note: For the most recent information on amendments, please consult the official online version of the TCPS at www.pre.ethics.gc.ca.