

Guidance for Case Reporting/REB Submission

The purpose of this document is to provide guidance on when a case report requires Research Ethics Board (REB) submission.

The Tri- Council Policy Statement - Ethical Conduct for Research Involving Humans defines research as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Case reports generally involve the collection and presentation of detailed information about a particular patient to highlight an interesting condition, treatment, presentation or outcome. There is no intent to test a hypothesis via systematic analysis, analyze data or add to generalizable knowledge. Thus, a case report that documents the clinically indicated care of a single patient does not generally meet the definition of research that requires REB review.

However, a case report that plans to incorporate a systematic data analysis of treatments and outcomes to allow possible extrapolation of the results to a larger population may satisfy the definition of research and not considered a case report. For example, when a series of patients is being reviewed, investigators usually begin to ask specific questions and a systematic collection of data occurs. This moves the study closer to deriving generalizable knowledge and meeting the definition of research. The process of “testing and evaluating” the data that is generated through the patient series is what defines this activity as research. Therefore, a case series that incorporates data collection and data analysis to answer a research question must undergo REB review.

REB submission requirements and forms are available at:

<https://southlake.ca/research/#research-ethics-board>

Inquiries to available funding to support case report writing should be directed to the applicable SRHC Department Manager or Program Director.