nova scotia health
Research Ethics Board

REB Methodological Review Checklist

1. Background/Introduction

	Yes	No	N/A
Evaluative review of the state of current knowledge in area of research and indicative of how study builds on or extends on body of information			
Background describes the issue including incidence and prevalence, how it occurs, who is affected and how			
Background clearly states the rationale for the review and explain why the question(s) being asked are important			
Results of any (related) pilot studies are presented			

2. Study objectives and specific research question(s)

The main objective of the study is specified in terms of problem, population, intervention(s) and comparison (s), and outcome(s) (both beneficial and harmful)			
There is a clearly stated research question and hypotheses			

3. Design and Methods

Study design, e.g. clinical trial (phase I, II, III); observational cohort study; case-control study; other is described			
The choice of study type is appropriate to the population, intervention(s), comparison(s) and outcome(s)			
Justification for study design choice, assumptions that accompany design choice and whether they can be reasonably met Limitations of design choice and mitigation strategies to reduce potential bias			
Target population, sample and recruitment methods are clearly described			
Study setting and timeframe are described			
Inclusion/exclusion criteria are clearly stated			
Provide appropriate justification for the exclusion of any population group			
Primary and secondary outcomes are clearly stated			
Planned intervention(s) and their timing is described			
Outcome measures pertaining to each objective are described (useful and appropriate)			
Anticipated drop-out or loss-to-follow up rate is described			
Plan for participant recruitment is described			
State whether participants who do not have the capacity to consent will be enrolled			

Plan for patient privacy protection included			
Observational study			
Predictors of interest along with potential confounders and effect modifiers are described			
Matching criteria described (if applicable)			
Duration of follow-up and timing of data collection is described			

4. Analysis plan

Description of how the sample size and power of the study were determined, including the statistical approach and any assumptions on which the calculations are based.*			
Specific statistical methods to be used to evaluate study objectives must be clearly stated. (what specific test will be used to test hypothesis)			
Specify how outcomes will be modelled (continuous, binary, etc.). If survey, how will responses be combined			
Description of all statistical tests for all planned analysis (primary, secondary and exploratory)			
Description of how covariates will be selected, if constructing a multi variable model			

** Pilot and exploratory studies do not need formal sample size calculations but a data analysis plan should still be included*

5. Data management

Methods for data entry and data management are described			
Mechanism for checking and editing data are described			
Data storage is described (where will the data be stored, data entry, access, security, validation, etc.)			
Approaches to dealing with missing data are described			
Methods of data collection and data management			
Description of how missing data will be dealt with			