

IH REB Minimum Requirements for a Protocol

A research protocol is a master document containing a complete and accurate picture of the work that will be undertaken and in particular how human participants will be involved in the research. The protocol should contain sufficient information so that the study could be repeated successfully, by another site, group or individual.

A protocol is not equivalent to a grant proposal, which aims to convey the necessary information to inform a panel of peers why a study should be funded, and that the individual or team has the skills to execute the research.

A protocol is also not equivalent to an IH REB Application for Ethical Review form, a UBC RISE Application, or another REB's application form. REB Application forms should demonstrate how a protocol that could apply at any research site will be applied to the Interior Health sites involved. Applicants should pay particular attention to how participants will be recruited at IH sites, how consent will be obtained from IH participants, and how study data will be collected and stored securely for the duration of the study.

Protocols should include, at a minimum:

1. A background literature review (with accompanying references) that includes an explanation of the justification for the study.
2. The study purpose
3. Hypotheses
4. Objectives
5. Specification of endpoints or outcomes (if applicable)
6. Research design including statistical analysis plan (if applicable) or justification of sample size, and
7. Detailed research procedures

Sample protocols are readily available online. The UBC Faculty of Medicine has a couple of simple [templates](#) that are appropriate for use with both clinical and behavioural research.