a place of mind
THE UNIVERSITY OF BRITISH COLUMBIA

Protocol Review Checklist

Study #	PI Name:	Study Nickname:
Primary Reviewer ☐	Secondary Reviewer ☐	Minimal Risk Reviewer ☐

A. REBA Comments:

I agree with the REBA comments with the following exceptions / qualifications /additions

None: ☐

As follows:

B. Study Summary: (Primary and Minimal Risk Reviewers Only)

Reviewer Introductory Notes or Comments

C. Conflict of Interest of the Researcher or his team

No Applicable COI Statements ☐ or

Comments: *(based upon information contained in Page 3, or otherwise)*

D. Qualifications of the Researcher and his team

No concerns ☐ **No knowledge of the PI's qualifications ☐ or**

Comments:

Scientific Considerations

1. **Background, Rationale, Objectives** *(clearly stated, objectives articulated, suitable justification, conduct of the study and achievement of outcomes are feasible)*
   ☐ **Satisfactory*** ☐ **Not satisfactory or clarification required**
2. **Social and Scientific Merit** *(research is important, significant, likely to generate useful information)*
   ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**
3. **Research Design and Methodology** *(methodology and data analysis adequately described and consistent with sound design, adequate peer review, sample size justified, procedures appropriate and don't expose participants to unnecessary risk, inclusion / exclusion criteria appropriate, equipoise is present, use of placebo is justified, over-all study design doesn't expose participants to unnecessary risk)*
   ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**

Comments/Other Issues:

Ethical Considerations

4. **Population** *(selection criteria equitable and appropriate, justification for use of vulnerable populations, special or additional safeguards if appropriate)*
   ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**
5. **Recruitment** *(no coercion, undue influence, access to participants and /or their records authorized and appropriate, confidentiality respected, script appended, compensation appropriate)*
   ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**
6. **Risk / Benefit** *(risks reasonable to benefits, adequately assessed, not over or understated, procedures necessary and reasonable, risks minimized)*
   ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**
7. **Privacy** *(Adequate provisions made to respect privacy of participants and maintain confidentiality of data)*
   ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**

Comments:

Safety Considerations

8. **Adequate provisions for monitoring** *(appropriate for study, describes who will monitor, when, plan for communication, termination or stopping as appropriate)*
   ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**
9. **Appropriate assessment of level of risk** *(PI has appropriately assessed impact of study on participants)*
   ☐ **Yes** ☐ **No or clarification required**
10. **Controversial research or higher level/ more frequent monitoring and verification required**
    ☐ **No** ☐ **Yes or clarification required**

Comments:

Informed Consent/Assent Considerations *(please refer to the Informed Consent /Assent Checklist-Template)*

11. **Language:** *(If there is language that should be changed, omitted or added, note below, indicating page, paragraph and section heading (where applicable)*
    ☐ **Satisfactory** ☐ **Changes Required**
12. **Waiver:** *(Any requested waiver or alteration to informed consent is properly justified)*
    ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**
13. **Competence:** *(Are participants competent, issues concerning competency adequately addressed)*
    ☐ **Satisfactory** ☐ **Not satisfactory or clarification required**

Comments:

Additional Comments *(including concerns with other documents, your suggested recommendation: approval, provisos, deferral if appropriate)*

**Satisfactory includes not applicable by implication, i.e. if the issue is not applicable, and is not dealt with in the application, it has been satisfactorily addressed.*