

Fraser Health Research Ethics Board Review Criteria	
Study Protocol/Proposal Scientific & Technical Issues	
1	Is the rationale for the study clearly stated in the context of present knowledge?, (e.g. is there Clinical Equipoise?)
2	Is the Hypothesis/research question to be tested fully explained?
3	Is the project design scientifically sound? (i.e. can it answer the hypothesis/research question?)
4	Is there a criterion to withdraw or withhold standard therapies for the purpose of the research and justification for such action?
5	Is the control arm adequate?, (if applicable)
6	Are the inclusion and exclusion criteria complete and appropriate?
7	Are the types and methods for subject allocation appropriate and fair?
8	Are the drugs and/or devices to be used fully described?
9	Are the clinical procedures to be carried out fully described and appropriate?
10	Is the statistical basis for the study design appropriate and is the plan for analysis of the data appropriate?
11	Is the study appropriately powered to answer the research question?
12	Are provisions provided to break the code of a double-blind study in an emergency situation?, (if applicable)
13	Are provisions provided for data monitoring procedures while the research is ongoing? This must include details of planned interim analyses and reporting.
14	Is there a criterion for prematurely withdrawing research participants?
15	Is there a criterion for suspending or terminating the research as a whole?

Fraser Health Research Ethics Board Review Criteria

Study Protocol/Proposal Ethical Issues

1	Is a vulnerable population being studied?
1a	Is the justification for studying this vulnerable population adequate?
1b	Have adequate provisions been made to ensure that the vulnerable population is not being exploited?
2	Is the social value of the study fully explained?
3	Have the risks vs. the benefits ratio (i.e. the risks-benefits ratio) for the research participants been discussed in the protocol?
3a	Have the risks been properly identified in the consent form?
4	Do provisions exist in the protocol for counselling research participants during and after the research? (if applicable)
5	Do provisions exist in the protocol to deal with adverse reactions associated with the research (medical/physical/emotional/psychological)?
6	Is the site where the study will be carried out adequate, including support staff, available facilities and emergency procedures?
7	Does the Principal Investigator have suitable qualifications and experience to carry out the study?
8	Is the design of the questionnaire / survey standardized? If not standardized, then this should be commented on.
9	Are questionnaires, diary cards, etc. being used in the research? <ul style="list-style-type: none"> a. Are these provided in English and/or translated documents if applicable b. Are these written in lay language, and easily understood? c. Are these relevant to answering the research questions? d. Are these worded sensitively?

References

1. World Health Organization, Research Ethics Review Committee (ERC) Checklist for Principal Investigators.
2. Forum of Ethics Review Committees, Sri Lanka FERCSL 2007. Ethics Review Committee Guidelines "A Guide for Developing Standard Operating Procedures for Committees that Review Biomedical Research Proposals."
3. REC Review Checklist Template Document No. HA RE001F5, Revision No. 01 (Latest version in HA intra-net)