



Amendment Checklist (include with REB Package)

The following documents are to be submitted with the Amendment Form. Applications submitted on outdated forms or incomplete application packages will be returned to the Investigator which may delay REB Review.

- No Funding Available
or
 Grant (check if applicable)
or
 Industry Sponsored (check if applicable)
- _____ Date Revised Clinical Trial Agreement and Detailed Study Budget Worksheet forwarded to Office of Research for legal review (if not applicable, indicate n/a)

Packages must be assembled in the order outlined on the checklist.

- Completed typed and signed REB Amendment Form (**11 copies**)
- Itemized HRH budget Spreadsheet (if applicable) outlining all procedures & visits for the study as per the study plan signed by PI (**11 copies**)
- Detailed Sponsor Budget Worksheet (if applicable) (**11 copies**)
- Amended Research Protocol or Proposal (tracked mode or highlighted) (NB - Commercial sponsors will provide you with **5 copies**)
- Amended Study Information & Informed Consent Form(s)/Assent Form(s) (conforming to the current HRH consent form template) (**11 copies in tracked mode, 1 clean copy**)
- Product Monograph or Investigator Brochure (where applicable) (**5 copies**)
- Patient related information (wallet card, patient info letter, etc.) (**11 copies**)
- Questionnaire/study instrument(s), data collection forms to be used in carrying out the research (**11 copies**) (where applicable)
- All other recruitment tools e.g. information letters, advertisements, posters, notices (**11 copies**)
- Evidence of REB approval in other jurisdictions where the research is to be conducted (**5 copies**) (where applicable)
- Health Canada No Objection Letter (**5 copies**) Not applicable

Research Team's Curriculum Vitae & Current Licenses (for new team members) (**1 copy**). CV's and Licenses are to be updated and forwarded to the REB Office on a yearly basis

- Attached On File with REB Office