University of Manitoba

Amendments, Additions or Changes to Approved Studies - Delegated Review

Submission Requirement Checklist
Research Ethics - Bannatyne

Failure to provide appropriate documentation as per conditions documented below will result in application being returned to the submitter. The submission deadlines will still apply if resubmission is required and may result in submission being considered only for the next deadline.

When submitting files to the Research Ethics Board (REB) number the documents in the same order as they occur in the Check List. *Ex. 01 Checklist; 02 Cover Letter, 03 Submission Form, 04 Submission Signature form, etc.* If this is not done the submission will be returned.

All current forms can be accessed from our website - Click Here

Document Required for Amendments *All documents must be dated.*		Yes	No	N/A
SUBMISSION REQUIREMENTS CHECKLIST	**Retain a copy of this checklist for your records. A copy of the checklist is not required with submission.**			
Bannatyne Campus Amendment Research Ethics Board Submission Form • *List all documents applicable to submission in Question # 9.* • *All questions must be completed in full. Do not reference the protocol or attach pages of protocol unless specifically requested in the questions on the form.* • *Review response to questions to ensure they are consistent with protocol, consent forms and supporting documents.* • *Ensure that if there are changes to recruitment and consenting processes that they are sufficiently outlined in Question 13 or the Amendment Summary.*		☐	Required for all additions or amendments	☐
PI or Delegate Signature and date on Amendment Research Ethics Board Submission form		☐	Required	Required
Amended or New Pre-screening and Screening Form(s)/Questionnaires including Phone Screening Forms: • Updated version date included on each document		☐	☐	☐
Amended or New Participant Information and Consent Form(s) – if applicable: • All changes must be clearly marked by either bolding (**new text**) or strike through (~~deleted text~~) for ease of review. • Clean copies no longer required. • Update version date in footer of each page.		☐	☐	☐
Amended or New Participant Letters and/or e-mails of Invitation to Participate - if applicable: • All changes must be clearly marked by either bolding (**new text**) or strike through (~~deleted text~~) for ease of review. • Clean copies no longer required. • Update version on cover page and if appropriate the footer of each page.		☐	☐	☐
Amended Protocol / Amendment Summary: • *All changes must be clearly marked by either bolding (**new text**) or strike through (~~deleted text~~) for ease of review.* • *Clean copies no longer required.* • *Update version on cover page and if appropriate in the footer of each page.*		☐	☐	☐

Document Required for Amendments *All documents must be dated.*		Yes	No	N/A
Amended or New Questionnaires/Scales/ Instruments Appendix with version date - if applicable: • *Prepare Questionnaire Appendix (date the appendix) with a cover page listing all documents and updated version dates.* • *All changes must be clearly marked by either bolding (**new text**) or strike through (~~deleted text~~) for ease of review.* • *Clean copies no longer required.* • *Update version on cover page and if appropriate the footer of each page.*		☐	☐	☐
Amended or New Advertisements and Recruitment material including social media documentation Appendix with version date - if applicable: • *Prepare Recruitment Appendix (date the appendix) with a cover page listing all documents and updated version dates.* • *All changes must be clearly marked by either bolding (**new text**) or strike through (~~deleted text~~) for ease of review.* • *Clean copies no longer required.* • *Update version on cover page and if appropriate the footer of each page.*		☐	☐	☐
Amended or New Data Collection Forms and Master Lists - If applicable. Required for all Retrospective Records Review applications. • *All changes must be clearly marked by either bolding (**new text**) or strike through (~~deleted text~~) for ease of review.* • *Clean copies no longer required.*		☐	☐	☐
Supporting Documents - if applicable: E.g. Aboriginal consultation, School board approvals, etc.		☐	☐	☐
Revised Study Budget - if applicable.		☐	☐	☐
Health Canada approval letters for Clinical Trials involving drugs, biologics, medical devices and natural health products - if applicable. This may include any of the following: • *"Letter of No Objection" (NOL), or "Acknowledgement of Receipt" for amendments for Clinical Trial Applications (CTA) involving drugs and/or biologics.* • *"Investigational Testing Authorizations" (ITA) for Medical Devices.* • *"Notice of Compliance" (NOC) for Natural Health Products.* **NOTE:** if this documentation is not available at the time of submission an approval certificate will not be issued until receipt. **DATE Expected** _____		☐	☐	☐
Amendment Involved Change in PI/Study Staff • *If there is a change in PI or study personnel this must be submitted on the **Change in Study Personnel** Form* • *If the amendment only involves a change in study personnel the main amendment form is not required*		☐	☐	☐

Retain a copy of this checklist for your records. A copy of the checklist is not required with submission.