University of Manitoba

Amendments, Additions or Changes to Approved Studies - Full Board 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

PI _____ HS _____ REB Reference H/B Year Number _____

Document Required for Amendments *All documents must be dated.*		Yes	No	N/A
SUBMISSION REQUIREMENTS CHECKLIST		☐	Required	
Bannatyne Campus Amendment Research Ethics Board Submission Form • *List all documents applicable to submission in Question # 10.* • *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 Questions 11 and 12b or the Amendment Summary.*		☐	Required	☐
PI or Delegate Signature and date on Amendment Research Ethics Board Submission form		☐	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 the footer of each page.*		☐	☐	☐

Document Required for Amendments *All documents must be dated.*		Yes	No	N/A
Amended or New Questionnaires/Scales/Instrument • *Prepare cover page for Questionnaire Appendix listing all documents and 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 r • *Prepare cover page for Recruitment Appendix/package listing all documents and 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.* • *Update version on Appendix cover page and if appropriate the footer of each page.*		☐	☐	☐
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 it will be listed on the Letter of Conditional Approval. **DATE Expected** _____		☐	☐	☐

Document Required for Amendments *All documents must be dated.*		Yes	No	N/A
Amendment Involved Change in PI/Study Staff • *If there is a change in PI this must be submitted the Change in* • *If the only amendment is a change to PI/Staff the other regular Amendment Form is not required.*		☐	☐	☐

Step-by-step instructions for submitting electronically

Create a zip folder of all applicable files per checklist and label it as the PI's name followed by the month of the scheduled meeting deadline. The zip folder reduces the size of the file and will hopefully make it easier when sending via email.

Prepare a separate folder for the Investigator's Brochure(s), Product Monograph(s) or safety reports. We are concerned the size of these files may create issues when sent via e-mail. This may require a second email when sending.

Send the zip folder to the bannreb@umanitoba.ca only. Do not send it to any of the REB staff's personnel email accounts.

Enter the following information as the email subject line as applicable to the submission:

Allowzip Full Board Amendment - Month and year of meeting deadline A - PI name and REB (HREB or BREB)

Save As | Print Form | Reset Form

April 2023