



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.

PI _____	HS _____	REB Reference H/B Year Number _____		
Document Required for Amendments <i>All documents must be dated.</i>	Paper Copies Required	Yes	No	N/A
SUBMISSION REQUIREMENTS CHECKLIST	3	<input type="checkbox"/>	Required	
Bannatyne Campus Amendment Research Ethics Board Submission Form <ul style="list-style-type: none"> • 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. 	3	<input type="checkbox"/>	Required	<input type="checkbox"/>
PI or Delegate Signature and date on Amendment Research Ethics Board Submission form	3	<input type="checkbox"/>	Required	<input type="checkbox"/>
Amended or New Pre-screening and Screening Form(s)/Questionnaires including Phone Screening Forms: <ul style="list-style-type: none"> • Updated version date included on each document 	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amended or New Participant Information and Consent Form(s) – if applicable: <ul style="list-style-type: none"> • 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. 	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amended or New Participant Letters and/or e-mails of Invitation to Participate - if applicable: <ul style="list-style-type: none"> • 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. 	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amended Protocol / Amendment Summary: <ul style="list-style-type: none"> • 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. 	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Document Required for Amendments <i>All documents must be dated.</i>	Paper Copies Required	Yes	No	N/A
<ul style="list-style-type: none"> • 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. 	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> • 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. 	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amended or New Data Collection Forms and Master Lists - If applicable. Required for all Retrospective Records Review applications. <ul style="list-style-type: none"> • 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. 	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Supporting Documents - if applicable: E.g. Aboriginal consultation, School board approvals, etc.	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Revised Study Budget - if applicable.	3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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: <ul style="list-style-type: none"> • "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 _____	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Document Required for Amendments <i>All documents must be dated.</i>	Paper Copies Required	Yes	No	N/A
Both HREB and BREB Submissions Required <ul style="list-style-type: none"> • <i>Electronic copy on flash drive(will be returned) or CD</i> • <i>E-mail electronic copies are not accepted.</i> 	1	<input type="checkbox"/>	Required	<input type="checkbox"/>
Amendment Involved Change in PI/Study Staff <ul style="list-style-type: none"> • <i>If the only amendment is a change to PI/Staff the other regular Amendment Form is not required.</i> 	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Return completed forms to: University of Manitoba Research Ethics - Bannatyne
P126-770 Bannatyne Avenue
Winnipeg, MB R3E 0W3
Phone: (204) 789-3255

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