



New Studies for Full Board Review Submission Requirement Checklist

Research Ethics - Bannatyne

(Purely Retrospective Records Review have separate submission checklist which is included on the form.)

All new study submissions **must** be either hand delivered or couriered to the office by the appropriate submission deadline date posted on the website.

Documents must be **collated by the submitter** into 4 full packages and 7 regular packages (including the Cover letter, Research Ethics Board Submission Form and Consent forms) **in order listed below**. Single copy requests should be included in 1 of the full packages. All documents must be staples separately in each collated package.

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

PI _____ Sponsor Protocol _____

Documents Required <i>All documents must be dated.</i>	Paper Copies Required	Yes	No	N/A
SUBMISSION REQUIREMENTS CHECKLIST	1	<input type="checkbox"/>	Required	
Cover Letter <ul style="list-style-type: none"> List study title in full. Identify appropriate Research Ethics Board (HREB or BREB) for review submission. Review Question # 1.0 of the Research Ethics Board (REB) submission form to assist with the appropriate selection. List all items and # of copies provided. List the items (including version date and version number) in letter as to be documented on final approval certificate. 	11	<input type="checkbox"/>	Required	
<ul style="list-style-type: none"> PI signature, and if applicable, supervisor signature for student projects must be included at time of submission. All information must be typewritten in space provided. All questions must be completed in full. Do not only reference the protocol or attach pages of protocol unless specifically requested in the questions on the form. Each form must be STAPLED. Department Head Signature required. Review response to all questions to ensure consistency with protocol, consent forms and supporting documents. 	11	<input type="checkbox"/>	Required	<input type="checkbox"/>
Department Head or Delegate Signature on Research Ethics Board Submission Form: <ul style="list-style-type: none"> If Principal Investigator (PI), Co-PI or research coordinator is also the Department Head then a delegate must sign attesting to the scientific merit of the study. If unable to obtain this signature prior to submission deadline date please indicate so on the cover letter. NOTE: The department head (or appropriate delegate) signature will be required prior to the study being reviewed at the full board meeting date or the protocol will be deferred until the next meeting date. 	Photocopies of originals are acceptable. 1 REB submission form must have signatures.	<input type="checkbox"/>	<input type="checkbox"/> Will submit prior to the full board meeting date	<input type="checkbox"/>
Participant Information and Consent Form(s) (if applicable): <ul style="list-style-type: none"> Required elements of Informed Consent included as per Bannatyne Campus Consent Form templates. First page on appropriate letterhead. If more than 1 consent is enclosed each form must be appropriately labelled in the title on page 1 (e.g. Screening, Focus group, Control group, Genetic, etc.). Version date, pagination(x of y) and spot for participant initials in footer of each page. 	11	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Documents Required <i>All documents must be dated.</i>	Paper Copies Required	Yes	No	N/A
<ul style="list-style-type: none"> Such documentation may be appropriate in lieu of signed consent for collection of anonymous or de-identified data via on-line survey and/or mail-returned questionnaires. Review <u>Bannatyne Consent Disclosure Document</u> for required elements. 	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Pre-screening and Screening Form(s)/Questionnaires including Phone Screening Forms (if applicable)	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant Letters and/or E-mails of Invitation to Participate (if applicable)	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	4	<input type="checkbox"/>	Required	
<ul style="list-style-type: none"> Prepare Questionnaire Appendix (date the appendix) with a cover page listing all documents and version dates. REQUIRED if submission includes 2 or more questionnaires, etc.). Each questionnaire, etc. should be coded (no direct identifiers) and linked to direct identifiers via a Master list All questionnaires should be collated and stapled to Appendix cover page NOTE: Final Approval Certificate will list the Questionnaire Appendix rather than listing each specific questionnaire/scale or instrument. 	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Prepare Recruitment Appendix (date the appendix) with a cover page listing all documents and version dates. REQUIRED if submission includes 2 or more advertisements, etc.). All documents should be labelled, collated and stapled to Appendix cover page NOTE: Final Approval Certificate will list the Recruitment Appendix rather than listing each specific questionnaire. 	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Participant Contact Information or Demographic Form (if applicable):				
<ul style="list-style-type: none"> Direct Identifiers (i.e. name, address, etc.) should be collected on a separate form (Master List) from data forms (including questionnaires, scales, instruments) and linked to study documentation via a unique study/participant code. 	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Required for all Retrospective Records Review applications.	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Supporting Documents (if applicable): (e.g. Aboriginal consultation/approvals, School board approvals, local ethics approvals for international projects, etc.)	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Study Budget:				
<ul style="list-style-type: none"> "For Profit" sponsored studies: appropriate contact information including contact name, contact e-mail address and telephone number must be provided in Research Ethics Board submission form. 	4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Documents Required <i>All documents must be dated.</i>	Paper Copies Required	Yes	No	N/A
Diaries, Patient Contact Cards and Retention Items (if applicable): <ul style="list-style-type: none"> NOTE: If there are several patient diaries which are similar submit only one diary and produce a cover page listing all diaries. The office will retain one diary, a photocopy of the first page of all other similar diaries and the cover page produced by the site. The office will return the diaries to your attention. Prepare "Diaries, Patient Contact Cards and Retention Items" Appendix (date the appendix) with a cover page listing all documents and version dates. REQUIRED if submission includes 2 or more documents in this category. A photocopy picture of patient retention items is acceptable. NOTE: Final Approval Certificate will list the Appendix rather than listing each specific diary, patient contact form or retention item. 	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<ul style="list-style-type: none"> Template signed and dated by PI for each calendar year. CV template previously signed in January of current year will be accepted. Please submit with each application even if previously submitted. 	1	<input type="checkbox"/>	Required	
Investigators Brochure or Product Monographs (if applicable): <ul style="list-style-type: none"> Usually required for clinical trials involving an investigational study medication or natural health products. 	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health Canada approval letters for Clinical Trials involving drugs, biological, 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 new studies and amendments for Clinical Trial Applications (CTA) for 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"/>
<ul style="list-style-type: none"> NOTE: If not completed by submission deadline date this will be listed on the Letter of Conditional Approval. 	1	<input type="checkbox"/>	<input type="checkbox"/> Will submit with response to conditions	<input type="checkbox"/> Previously submitted to the ethics office
Health Research Ethics Board (HREB) Submission only: <ul style="list-style-type: none"> Electronic copy on flash drive(will be returned) or CD E-mailed electronic copies are not accepted. 	1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

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