New Studies for Full Board Review
Submission Requirement Checklist
Research Ethics - Bannatyne

REB Used Only

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

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 _____ Sponsor Protocol _____

Documents Required *All documents must be dated.*		Yes	No	N/A
SUBMISSION REQUIREMENTS CHECKLIST		☐	Required	
Cover Letter • *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.*		☐	Required	
Research Ethics - Bannatyne Submission Form: • *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.* • *Department Head Signature required.* • *Review response to all questions to ensure consistency with protocol, consent forms and supporting documents.*		☐	Required	☐
Department Head or Delegate Signature on Research Ethics Board Submission Form: • *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.*		☐	☐ Will submit prior to the full board meeting date	☐
Participant Information and Consent Form(s) (if applicable): • *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.*		☐	☐	☐

Documents Required *All documents must be dated.*		Yes	No	N/A
Consent Disclosure Statement (if applicable): • *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 Bannatyne Consent Disclosure Document for required elements.*		☐	☐	☐
Pre-screening and Screening Form(s)/Questionnaires including Phone Screening Forms (if applicable)		☐	☐	☐
Participant Letters and/or E-mails of Invitation to Participate (if applicable)		☐	☐	☐
Protocol		☐	Required	
Questionnaires/Scales/Instruments Appendix with version • *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.*		☐	☐	☐
Advertisements/Recruitment/Social Media Appendix with • *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.*		☐	☐	☐
Participant Contact Information or Demographic Form (if applicable): • *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.*		☐	☐	☐
Data Collection Forms and Master Lists (if applicable): *Required for all Retrospective Records Review applications.* • See Forms and Templates link for examples.		☐	☐	☐
Supporting Documents (if applicable): (e.g. Aboriginal consultation/approvals, School board approvals, local ethics approvals for international projects, etc.,)		☐	☐	☐
Study Budget: • *"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.*		☐	☐	☐

Documents Required *All documents must be dated.*		Yes	No	N/A
Diaries, Patient Contact Cards and Retention Items (if applicable): • *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.*		☐	☐	☐
Bannatyne Campus Curriculum Vitae Template: • *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.*		☐	Required	
Investigators Brochure or Product Monographs (if applicable): • *Usually required for clinical trials involving an investigational study medication or natural health products.*		☐	☐	☐
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: • *"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:*		☐	☐	☐
TCPS 2 "Course on Research Ethics" (CORE) REQUIRED: • *NOTE: If not completed by submission deadline date this will be listed on the Letter of Conditional Approval.*		☐	☐ Will submit with response to conditions	☐ Previously submitted to the ethics office

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 New Study - Month and year of meeting deadline A - PI name and REB (HREB or BREB)

Save As | Print Form | Reset Form

April 2023