UNIVERSITY OF MANITOBA

New Studies for Delegated 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** in the same order as below (Checklist, Cover Letter, Bannatyne Submission Form, etc.).
- **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.
- Please review the **DELEGATED REVIEW GUIDELINES** prior to preparing your submission to ensure the study qualifies for delegated review.

Documents Required *All documents must be dated.*	Paper Copies Required	Yes	No	N/A
SUBMISSION REQUIREMENTS CHECKLIST	1	☐	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.*	1	☐	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.* • *Each form must be STAPLED.* • *Department Head Signature required.* • *Review response to all questions to ensure consistency with protocol, consent forms and supporting documents.*	1	☐	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.*	1	☐	☐	
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 one consent is enclosed each form must be appropriately **labelled** in the title on page 1(e.g. Screening, Focus group, Control group, Genetic, etc.).* • ***REQUIRED** Version date, pagination(x of y) and spot for participant initials in footer of each page.*	1	☐	☐	☐

Documents Required *All documents must be dated.*	Paper Copies Required	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.*	1	☐	☐	☐
Pre-screening and Screening Form(s)/Questionnaires including Phone Screening Forms (if applicable)	1	☐	☐	☐
Participant Letters and/or e-mails of Invitation to Participate (is applicable): • *Such documentation may be appropriate in lieu of signed consent for collection of anonymous data via a mail returned survey or on-line survey.* • *Please review Bannatyne Consent Disclosure documents for required elements (if applicable).*	1	☐	☐	☐
Protocol	1	☐	Required	
Questionnaires/Scales/Instruments Appendix with version date (if applicable): • *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.*	1	☐	☐	☐
Advertisements/Recruitment/Social Media Appendix with version date (if applicable): • *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.*	1	☐	☐	☐
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.*	1	☐	☐	☐
Data Collection Forms and Master Lists (if applicable): ***REQUIRED*** *for all Retrospective Records Review applications.* • See Forms and Templates link for examples.	1	☐	☐	☐
Supporting Documents (if applicable): *(e.g. Aboriginal consultation/approvals, School board approvals, local ethics approvals for international projects, etc.,)*	1	☐	☐	☐
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.*	1	☐	☐	☐

Documents Required *All documents must be dated.*	Paper Copies Required	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.*	1	☐	☐	☐
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.*	1	☐	Required	
Investigators Brochure or Product Monographs (if applicable): • *Usually required for clinical trials involving an investigational study medication or natural health products.*	1	☐	☐	☐
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:*	1	☐	☐	☐
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.*	1	☐	☐ Will submit with response to conditions	☐ Previously submitted to the ethics office
Health Research Ethics Board (HREB) Submission only: • *Electronic copy on flash drive(will be returned) or CD* • *E-mailed electronic copies are not accepted.*	1	☐	☐	☐

September 2017