

Instructions for Completing the Toronto Academic Health Sciences Committee (TAHSC) Application Form

This form is intended to be completed electronically, printed, signed and submitted in hard copy to the St. Michael's Hospital Research Ethics Board. 30 copies of the application form and the consent form are required to be submitted, including 6 packages with copies of the Protocol, Investigator's Brochure and/or other supporting information. (For expedited reviews, see below).

This form was drafted for use by Principal Investigators (hereinafter "PI") and their staff to assist in streamlining the application process for new study applications. This will also ensure consistency in the type of information received, and assist the REB in assessing the scientific and ethical basis of the study.

The application form will not be accepted if it is not signed by the PI (or faculty supervisor) in question 4A (Page 2) and by any Co-Investigators in question 4B of the application form.

This application must be accompanied by:

1. The consent form, or a detailed justification for not using a written consent form (see Tri-Council Policy Statement Article 2.1 (c));
2. Data collection forms, case report forms, questionnaires, subject recruitment methods, subject information cards, etc. being used in the study;
3. Protocol or details of how the study will be conducted;
4. Investigator's Brochure for clinical trials, and/or any other information deemed by the PI to be relevant to the REB should be included or attached to this form;
5. Relevant reviewer comments from a scientific review of the study undertaken prior to submission of the application form (as requested in question 8).
6. **Appendix to TAHSC Application Form (PHIPA Appendix) which provides additional information required by the Personal Health Information Protection Act, which came into force on November 1, 2004 (see the PHIPA Appendix).**

If any of the following are being requested, please justify in detail in the application form, or in an accompanying letter:

- Expedited review for a minimal risk study (only 4 copies of the application and supporting documents are required)
- Recruitment of study subjects from staff or students at the hospital
- Genetic or DNA analysis of samples
- Database development.

Please note that the Research Ethics Board is prepared to accept the use of either of the terms "subject" or "participant", as preferred by the PI; however, one term should be used consistently.

The PHIPA Appendix document must be completed and submitted with any study proposal in which personal health information is used.