

St. Michael's Hospital Research Ethics Board Submission Checklist

Application Contents

- TAHSN Human Subjects Research Ethics Application – **all** sections completed ____ copies
(30 copies Full Board/4 copies Delegated)

- All Signatures obtained
 - Principal Investigator
 - Co-Investigator(s)
 - Division/Dept/Program Signature – **cannot** be one of the Investigators

- Protocol - **mandatory** (6 copies Full Board/4 Copies Delegated) ____ copies

- Health Canada Authorization letter ie 'No Objection Letter',
Acknowledgement of Receipt, Notice of Authorization – ____ copies
mandatory for drug, device & natural health product studies

- Investigator's Brochure/Product Monograph ____ copies
(If applicable, 6 copies Full Board/4 copies Delegated)

- PHIPA Addendum – **mandatory only if current TAHSN application not used**
(30 copies Full Board/4 copies Delegated) ____ copies

- Patient Information and Consent Form ____ copies
(30 copies Full Board/4 copies Delegated)

If applicable, the following documents should also be included (30 copies Full Board/4 copies Delegated):

- Consent form meets SMH Consent Form Guidelines (version September 22, 2005)
 - Consent Form on SMH Letterhead
 - Standard Headings
 - Standard Clauses
 - Readability (Grade 7 level recommended)
 - Appropriate Signature Page
 - Risk estimates included
 - Formatting (>10 pt. font, page numbering, short study title in footer, etc.)

- If participants are under 16, assent form included

- Questionnaire/data collection form/study instrument included

- Recruitment poster/advertisement on SMH template

- Copy of peer review, REB correspondence/REB approval letters from other sites

Note: Incomplete applications will not be accepted for review.
All applications are to be collated by the investigator prior to submission.