**Initial Research Submission Checklist**

For more information and our current forms, please visit our website at: <https://www.tehn.ca/education-research/research/research-ethics-board-reb/research-ethics-board-reb-forms>

**Please note the following when considering the level of review:**

**TCPS 2 (2018) — Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans**

**Article 6.12** In keeping with a proportionate approach to research ethics review, the selection of the level of REB review shall be determined by the level of foreseeable risks to participants: the lower the level of risk, the lower the level of scrutiny (**delegated review**); the higher the level of risk, the higher the level of scrutiny (**full board review**).

Required = 🗸 Not required = 🗴 Include if applicable =☉

| **Item** | **Delegated** | **Full Board** |
| --- | --- | --- |
| [ ]  | CVs (must include date) – All MGH Investigators and Lead Principal Investigator (if the Lead Principal investigator is not the MGH PI) | 🗸 | 🗸 |
| [ ]  | Tri-Council Policy Statement 2 (TCPS 2) 2022 Tutorial Certificate(s) for **each team member** | 🗸 | 🗸 |
| [ ]  | Privacy Training for Research Personnel Module Certificate(s) for **each team member** (new 2022 module available at link above) | 🗸 | 🗸 |
| [ ]  | Health Canada Division 5-Drugs for Clinical Trials Involving Human Subjects (Division 5) Certificate | ☉ | ☉ |
| [ ]  | Good Clinical Practice (GCP) Certificate | ☉ | ☉ |
| [ ]  | Responsible Conduct of Research (RCR) Certificate | ☉ | ☉ |
| [ ] [ ]  | N2 Investigator Standard Operating Procedures (SOP) training are required to be completed within six weeks of REB submission. MGH investigators will be enrolled at time of their REB submission with the exception of MGH Medical Education Learners (Residents).The following training certificates for each module below must accompany all resident initial research submissions to the REB:1. N2 Investigator Standard Operating Procedure Module 5
2. Submitting an Application to the Research Ethics Board (REB) Module
 | 🗸 | 🗸 |
| 🗸 | 🗸 |
| [ ]  | Research Administrative Fee & Copy of Research Administration Fee Invoice *(For industry sponsored studies)* | 🗴 | ☉ |
| [ ]  | Research Overhead Fees Recovery Form\* | ☉ | ☉ |
| [ ]  | Research Privacy Assessment Form# | ☉ | 🗴 |
| [ ]  | Toronto Academic Health Sciences Network (**TAHSN)** Research Application including all **required signatures**. | 🗸 | 🗸 |
| [ ]  | Clinical Trials Registration Number – Identify on TAHSN application  | 🗴 | ☉ |
| [ ]  | Protocol / Research Proposal  | 🗸 | 🗸 |
| [ ]  | Participant Informed Consent Form(s)*Please review the* [*Consent Form Checklist*](https://www.tehn.ca/documents/form/research-checklist-consent-form-and-layout) *for guidance and/or use the General Consent Form Template when drafting your consent form.*  | ☉ | 🗸 |
| [ ]  | Completed and signed Study Cost Estimate Forms (for any departments impacted by your research) | ☉ | ☉ |
| [ ]  | Questionnaires / Surveys | ☉ | ☉ |
| [ ]  | Data Collection Forms | ☉ | ☉ |
| [ ]  | Posters, Recruitment Fliers, Pamphlets, Brochures, Wallet Cards, Patient Diaries, etc. | ☉ | ☉ |
| [ ]  | Budget  | ☉ | 🗸 |
| [ ]  | Form 1572 *If applicable – for US industry sponsored studies* | 🗴 | ☉ |
| [ ]  | Investigator’s Brochure / Product Monograph | 🗴 | ☉ |
| [ ]  | Device Manual | 🗴 | ☉ |
| [ ]  | Health Canada No Objection Letter | 🗴 | ☉ |
| [ ]  | REB Approval Letters & Correspondence  | ☉ | ☉ |
| [ ]  | Thank you Letter to Study Participants | ☉ | ☉ |

**Additional Information:**

* There may be other items not listed/identified here that you may want to include with your submission.
* \*As of **January 1, 2020** TEHN implemented a new policy for the collection of Research Overhead Fees. This policy applies to all funded nonprofit and private sector research. Please complete and submit the form ***Research Overhead Fees Recovery*** form found in Policytech. Please submit this with your completed TAHSN Application.
* #As of **June 1, 2023** minimal risk studies eligible for delegated review are now required to complete a Research Privacy Assessment prior to project submission to the REB.

**Minimal Risk** (TCPS 2 2022, Article 2.8, Section B) definition:
*For the purposes of this Policy, “minimal risk” research is defined as research in which the probability and magnitude of possible harms implied by participation in the research are no greater than those encountered by participants in those aspects of their everyday life that relate to the research.*

*In their assessment of the acceptable threshold of minimal risk, REBs have special ethical obligations to individuals or groups whose situation or circumstances make them vulnerable in the context of a specific research project, and to those who live with relatively high levels of risk on a daily basis. Their inclusion in research should not exacerbate their vulnerability (Article 4.7).*

**Submission Requirements:**

* Do not combine documents into a single file. Each item must be a separate document.
* All documents must include the appropriate **version numbers**, **version dates**, and **page numbering in the correct format (x of y)** in the footer section. The MGH logo (available on iCare) must appear in the upper left-hand corner in the header section where applicable (i.e., participant facing documents).
* Electronic file names are not to exceed 40 characters including spaces. Names of files are to be in this format: **Type\_YearMonthDay\_VersionNumber**, see examples:
	+ E.g., Protocol\_2001Jan01\_V1.pdf; Protocol\_xyzabc\_2001Jan01\_V1.1.docx
	+ E.g., Consent\_ArmA\_2001Jan01\_V1.docx; ICF\_Parent\_2001Jan01\_V1.1.pdf
	+ E.g., Survey\_Pre\_2001Jan01\_V1.1.pdf; Survey\_Post\_2001Jan01\_V1.docx
	+ E.g., CRFs\_2001Jan01\_V1.docx; Data Collection Form\_2001Jan01\_V1.pdf

All files are to be submitted in either **MS Word format (.docx)**, or **Adobe format (.pdf)**.
Do not submit MS Excel files. Please convert these to either PDF or MS Word format.

Please submit one full electronic copy of your complete submission with all signatures, using the subject line “**New Study Submission**”, toResearchEthicsBoard@tehn.ca.

**Contracts:**

[ ]  Please submit word copies of all contracts/agreements, budget, and most recent/approved protocol toResearchContracts@tehn.ca