**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** |
| --- | --- | --- |
| [ ]  | Completed [MGH Research Intake and Approval Form](https://forms.office.com/pages/responsepage.aspx?id=zrAEUX-1UEmtdyib3BsCQ5XAES0UhG1Il3V5zW8lZZRUNlNWMlU5MUI0RUdNTDhCUFdRVlNXS0hZUS4u&route=shorturl)  | 🗸 | 🗸 |
| [ ]  | 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)* | 🗴 | ☉ |
| [ ]  | MGH Initial REB Application including all **required signatures**. | 🗸 | 🗸 |
| [ ]  | Appendix A: Conflict of Interest Declaration (If applicable)  | ☉ | ☉ |
| [ ]  | Appendix B: Study Personnel Log (Required)  | 🗸 | 🗸 |
| [ ]  | Clinical Trials Registration Number – Identify on MGH Initial REB 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.*  | ☉ | 🗸 |
| [ ]  | Questionnaires / Surveys | ☉ | ☉ |
| [ ]  | Data Collection Forms | ☉ | ☉ |
| [ ]  | Posters, Recruitment Fliers, Pamphlets, Brochures, Wallet Cards, Patient Diaries, etc. | ☉ | ☉ |
| [ ]  | Site Specific MGH 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 | ☉ | ☉ |

There may be other items not listed/identified here that you may want to include with your submission.

**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.