# AMENDMENT FORM

**NOTE TO RESEARCHERS**: Researchers who seek to implement any changes to an approved study must obtain the approval of the IRB before they proceed. The only exception is when the change is necessary to eliminate an immediate hazard to the participant; in this latter situation, the IRB must be notified immediately, and the modification submitted for review. Amendments may include, but are not limited to, modifications to the research design and methodology, modifications to the participant population or recruitment and consent procedures, and updates to the consent form.

At the discretion of the IRB Chair or Co-Chair, amendments may be reviewed via a delegated / expedited process. Significant revisions will require that the amendment be reviewed by the IRB Committee at a scheduled meeting.

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| **PRINCIPAL INVESTIGATOR:** | |
| **STUDY TITLE:** | |
| **IRB / INFO-ED STUDY NUMBER:** | |
| Please describe / explain the proposed study amendment and provide a justification for the change. A separate letter or page can be used to detail extensive or numerous changes. | |
| What follow-up action will be taken with participants already enrolled to the study? (E.g., re-consent be obtained, the changes do not apply to current participants; no action required.) | |

**Documentation**: The following documentation is required for an ethics review of the amendment:

- Signed and dated amendment submission form
- Revised study documents if applicable.

All amendment should be submitted by e-mail to: submit2irb.med@mcgill.ca. Amendments requiring a full Board review should be submitted to the IRB at least **one (1) week prior** to the scheduled meeting.

For additional information, please contact the IRB office.

**PI SIGNATURE:** **DATE:**