McGill | Faculty of Medicine and Health Sciences | Faculté de médecine et des sciences de la santé

Institutional Review Board - Serious Adverse or Unanticipated Events / Safety Reports Submission Form -

NOTE TO RESEARCHERS:

Please complete this form to report:

- **Adverse or unanticipated events:** Any unfavorable occurrence (physical, emotional or psychological) experienced by a person participating in a research study, which does not necessarily have to have a causal relationship with the study. These events shall be reported promptly (within 15 days) to the IRB.
- **Sponsor safety reports:** A summary of adverse or unanticipated events occurring outside the jurisdiction of this IRB, prepared by the study sponsor. The PI shall provide a listing of the reports and complete the last question of this form only.

Principal Investigator:

Study Title:

IRB Study Number:

Date of event:

Location:

DESCRIPTION OF EVENT (provide as much information as possible) _____

Was this adverse/unanticipated event attributed to a study procedure? Yes ☐ No ☐

Was the event unexpected? Yes ☐ No ☐

What action (if any) was or will be taken by the Research Team? _____

What follow-up action does the PI propose?:

- Inform study participants ASAP ____
- Revise the consent/assent forms and/or protocol (provide an amendment form) ____
- No action required _____
- Other (please describe) _____

SIGNATURE

Principal Investigator Date