## 

## Adverse Event Form

**STUDY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PARTICIPANT ID #: \_\_\_\_\_\_\_**

Describe the adverse event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Is this event a **new** event? \_\_\_\_\_

Is this event a change/resolution of an **ongoing** event? \_\_\_\_\_

Onset of Adverse Event (date/time): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Resolution of Adverse Event (date/time): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Is this event Serious? Yes ⬜ No ⬜

(Results in death, is life threatening, requires hospitalization, results in persistent or significant disability.)

Is this event intermittent? Yes ⬜ No ⬜

1. Rate Intensity (severity):

Mild Moderate Severe Life threatening

Different levels of intensity are defined as follows:

* Mild: Awareness of sign or symptom, but easily tolerated
* Moderate: Discomfort enough to cause interference with normal daily activities
* Severe: Inability to perform normal daily activities
* Life Threatening: Immediate risk of death from the reaction as it occurred

2. Is the adverse event is still present: Yes ⬜ No ⬜

3. Frequency: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

4. Relationship to experimental procedure (exercise or other procedure): Please circle one:

Not related Unlikely Possible Probable Definite

Relationship to the exercise training or other procedure:

* Not related: An adverse event which is not related to the study
* Unlikely: An adverse event for which an alternative explanation is more likely
* Possible: An adverse event which might be due to the study. An alternative explanation is inconclusive. The relationship in time is reasonable; therefore, the causal relationship cannot be excluded.
* Probable: An adverse event which might be due to the study. The relationship in time is suggestive (i.e., confirmed by dechallenge of the treatment). An alternate explanation is less likely.
* Definite: An adverse event which cannot be reasonably explained by alternative explanation. The relationship in time is very suggestive (e.g., it is confirmed by dechallenge and rechallenge).

Was treatment administered? Yes ⬜ No ⬜

Details: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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\* This is a **SERIOUS ADVERSE EVENT -** will be reported to the Research Ethics Board and your family physician (if permission is granted). Your name will not be disclosed to the Research Ethics Board.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If you have questions concerning the study you can contact Name of Principal Investigator or Faculty Supervisor at Phone number.

If you have any questions about your rights as a research subject or concerns about this study, you may contact the Chair of the University of Regina Research Ethics Board at (306) 585-4775 or email [research.ethics@uregina.ca](mailto:research.ethics@uregina.ca). Out of town participants may call collect.