University of Guelph

Research Ethics Board (REB)

Event Form

## REB Number

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## Principal Investigator

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## Research Personnel Present

Include information regarding (names and contact information) of all personnel.

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## Unique Subject Code

**Note**: Do not provide any personal information.

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## Description of Event

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## Type of Event you are reporting

[ ]  Incidental Findings (IF)

[ ]  Reportable Event (RE)

[ ]  Adverse Event (AE)

[ ]  Serious Adverse Event (SAE)

Describe:

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## Action Taken by Research Personnel

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## Date Reported to Ethics Office

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## Name and Contact Information of Person Reporting

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## Further Action Taken/Follow up Required

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## Date Reported to REB

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## Further Action Required by REB

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## Definitions

### Incidental Findings (IF)

Any unanticipated discoveries made in the course of research but that are outside the scope of the research. Material incidental findings are findings that have been interpreted as having significant welfare implications for the participant, whether health-related, psychological or social.

### Reportable Event (RE)

Any event (medical or other) which was not expected to occur during the course of the experimental protocol.

### Adverse Event (AE)

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

### Serious Adverse Event (SAE)

Any untoward medical occurrence that at any dose:

* Results in death,
* Is life-threatening,
* Requires inpatient hospitalization or prolongation of existing hospitalization,
* Results in persistent or significant disability/incapacity, or
* Is a congenital anomaly/birth defect.