

**REVIEW ETHICS BOARD:**

ADVERSE OR UNANTICIPATED EVENT(S) REPORT

**NOTE:** An **Adverse Event** is ANY unfavorable change in current health status (including mental, emotional, physical and/or psychological changes) in study participants/informants. This change MAY or MAY NOT be causally related to the study protocol.

An **Unanticipated Event** is any unfavorable or unintended occurrence during the course of research which may have immediate impact OR potential future impact on participants/informants.

**Use this form to report:**

* ANY Adverse Event occurring as part of an Algoma University REB-approved research study, including research approved by the AU REB but NOT conducted by AU faculty, students and/or staff.
* Any Unanticipated Event relevant to a research ethics protocol (e.g., health-related event, breach of confidentiality, protocol violation, participant complaint).



**SECTION A: TITLE & CONTACTS**

**TITLE OF RESEARCH PROJECT**

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**A2. PRINCIPAL INVESTIGATOR:**

| Title:        | Name:       |
| --- | --- |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

**A3. CO-INVESTIGATOR, FACULTY SUPERVISOR, FACULTY SPONSOR (VISITING RESEARCHER):** ☐ NOT APPLICABLE

| Title:        | Name:       |
| --- | --- |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

| Title:        | Name:       |
| --- | --- |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

| Title:        | Name:       |
| --- | --- |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

**ALTERNATE CONTACT(S)**: (e.g., Research Coordinator) ☐ NOT APPLICABLE

| Title:        | Name:       |
| --- | --- |
| Department:       | Institution/Organization:  |
| Mailing address (if NOT AU):       |
| Phone:        | Institutional E-mail:       |

**SECTION B: LOCATION OF EVENT & DESCRIPTION**

**B1.** Did the Adverse/Unanticipated Event occur at Algoma University? ☐ NO ☐ YES

**IF YES**, specify precise location of event, (e.g., on-campus, building, room no., off-side location, etc.)

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**IF YES,** was anyone at that site notified?☐ NO ☐ YES

**IF YES,** name who was notified and provide their contact information.

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**B2. DATE EVENT OCCURRED:**

**B3.** Provide a brief but detailed description of the event:

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**B4.** What IF ANY action has been taken, or will be taken, by the staff on the research sites (e.g., campus building, room, etc.) Please identify these individuals.

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**B5.** What IF ANY action has been taken or will be taken, by the research investigator, members of the research team, etc.?

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**SECTION C: STATEMENT BY PRINCIPAL INVESTIGATOR**

I am aware of, and understand the circumstances and/or information related to the adverse/unanticipated event(s). I have assessed the significance of this event with respect to participants/informants involved and as a result, I conclude that:

**C1.** The study *requires* change(s) to the protocols: ☐ NO ☐ YES

**C2.** The study *requires* change(s) to the Information Letter & Consent Form:

☐ NO ☐ YES

**IF YES, CHANGES ARE ANTICIPATED** to either, describe these changes & attach copies of ANY revised Protocols, Information or Consent Letter, for review by the REB.

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**SECTION D: SIGNATURES**

I CERTIFY, that the information provided in this application is complete and correct,

| PRINCIPAL INVESTIGATOR:        | Date:       |
| --- | --- |
| PRINCIPAL INVESTIGATOR:        | Date:       |

| CO-INVESTIGATOR:        | Date:       |
| --- | --- |
| CO-INVESTIGATOR:        | Date:       |
| CO-INVESTIGATOR:        | Date:       |
| FACULTY:        | Date:       |
| FACULTY SPONSOR:        | Date:       |

**\*\* IF** principal investigator is a student**,** their academic advisor **MUST** sign, indicating that they have reviewed the submission.

| ACADEMIC ADVISOR:        | Date:       |
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| ACADEMIC ADVISOR:        | Date:       |

\*\* Email digital copy, including ALL relevant appendices to: **ethics@algomau.ca**