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**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).

**NOTE:** When completing form, if question is **NOT APPLICABLE** enter ‘**N/A’** into appropriate field.

**SECTION A: TITLE & CONTACTS**

**TITLE OF RESEARCH PROJECT**

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**A2. Principal Investigator:**

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| 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

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| --- | --- |
| 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,

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| 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.

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

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