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| http://sharepoint.auroracollege.nt.ca/pf/Communications%20%20Print%20Templates/Logos/Aurora%20College%20Logo%20CMYK%20-%20vertical%20text%20on%20bottom.jpgAurora College Research Ethics CommitteeUnanticipated Event or Issue Report |  |

## Instructions

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| 1. | Complete all sections. Please write “N/A” if a section is not applicable to your research/training protocol. |
| 2. | Attach a copy of all relevant documentation or other items required for a complete review of your unintended event or issue report. |
| 3. | Submit this form to the Chair of the Research Ethics Committee via email – chairREC@auroracollege.nt.ca |
| Please submit this report as soon as possible following an unanticipated event (within 10 working days). |

## Project Identification

|  |  |  |  |
| --- | --- | --- | --- |
| Principal Investigator Name |  | REC Protocol # |  |
| Affiliation |  |
| Division/Faculty |  |
| Mailing Address |  |
| E-Mail Address |  | Phone Number |  |
| Project Title |  |

## Proposed Changes

1. Please provide the date of the event or the date on which the issue became apparent:
2. Please describe the event or issue, providing as much detail as possible for the REC:

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| http://sharepoint.auroracollege.nt.ca/pf/Communications%20%20Print%20Templates/Logos/Aurora%20College%20Logo%20CMYK%20-%20vertical%20text%20on%20bottom.jpgAurora College Research Ethics CommitteeUnanticipated Event or Issue Report |  |

1. What was the outcome of the event or issue?
2. How many participants were affected by the unanticipated event or issue?
3. Has the unanticipated event or issue changed the risks initially described to the REC and participants?

[ ]  Yes [ ]  No

a. If YES, please explain:

1. Has the unanticipated event or issue had other ethical implications that may affect participants’ welfare?

[ ]  Yes [ ]  No

a. If YES, please explain:

1. What actions have been taken, or will be taken, by the research team to address the situation (eg. revision of consent form, modification of protocol to reduce risks to participants, suspension of study)? (Please provide any relevant revised study documents.)

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| http://sharepoint.auroracollege.nt.ca/pf/Communications%20%20Print%20Templates/Logos/Aurora%20College%20Logo%20CMYK%20-%20vertical%20text%20on%20bottom.jpgAurora College Research Ethics CommitteeResearch Ethics Review Application Form |  |

## Signatures

Principal Investigator Name:

Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_