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| **ADVERSE AND SERIOUS ADVERSE EVENT REPORT** | |
| It is a condition of ethical approval that Adverse Events (AEs) and Serious Adverse Events (SAEs) are reported to the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee (DDVA HREC).  This report must be used to notify the DDVA HREC of AEs or SAEs that occur during a research project. For **SAE**s, the Principal Investigator (PI) must submit this report to DDVA HREC **within 72 hours.** For **AE**s, the PI must submit this report within **30 calendar days**.  Researchers will also need to include details on AEs and SAEs in their progress and final report.  Completed reports are to be emailed to [ddva.hrec@defence.gov.au](mailto:ddva.hrec@defence.gov.au). | |
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| **SECTION 1: PROJECT DETAILS** | |
| **Project Number:** |  |
| **Project Title:** |  |

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| **SECTION 2: PRINCIPAL INVESTIGATOR DETAILS** | |
| **Name:** |  |
| **Phone:** |  |
| **Email:** |  |

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| **SECTION 3: DETAILS OF EVENT** | | | | |
| **Date event occurred:** |  | | | |
| **Brief description:** (including location and number of participants affected) |  | | | |
| **Has the PI reported the event to the sponsor?** | Yes | No | | N/A |
| If no or N/A selected, please indicate why the sponsor was not notified of the event: | | | |
| **Relationship:** | Suspected related | | Probably related | |
| Unlikely related | | Not related | |
| **Immediate action taken:** |  | | | |
| **Subsequent action taken and/or required:** |  | | | |
| **Outcome:** |  | | | |

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| **SECTION 4: IMPLICATIONS** | | |
| **Does this event raise any additional safety concerns for participants?** | | |
| Yes | | No |
| If yes, please provide details. If no, please explain why: | | |
| **Will there be changes to the research protocol as a result of this event?** | | |
| Yes | | No |
| *Note: If changes are recommended to the protocol the Principal Investigator will need to submit a request for amendment and the revised forms (where appropriate).*  If yes, please provide details: | | |
| **Will there be changes to the Participant Information Sheet or Consent Form (PICF) as a result of this event?** | | |
| Yes | No | |
| *Note: If changes are recommended to the PICFs the Principal Investigator will need to submit a request for amendment and the revised forms (where appropriate).*  If yes, please provide details. If no, please explain why: | | |
| **Are there any other issues raised by this adverse event that may have wider implications?** | | |
| Yes | No | |
| If yes, please provide details and explain how you will address them: | | |

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| **SECTION 5: PRINCIPAL INVESTIGATOR DECLARATION** | | |
| I advise the following (please indicate): | | |
| Change to the protocol | Yes | No |
| Change to the PICF | Yes | No |
| Previously enrolled participants to be notified | Yes | No |
| The study to be stopped. | Yes | No |
| If yes, specify the action required: | | |
|  |  | |
| **Name** | **Signature** | |
| **Date:** | | |