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| JCU_Logo_RGB[1]_NEW_resize | HUMAN ETHICS APPROVAL NUMBER | H      |
|  | Version No.  |       |

**HUMAN RESEARCH ETHICS ADVERSE EVENT REPORT**

***Submission and completion guide:***

* ***All adverse events must be reported to the HREC***
* ***All questions are relevant to all projects, all questions must be completed***
* ***Additional rows/tables can be added to tables if required***
* ***Please email one pdf file of this report to*** ***ethics@jcu.edu.au******. If it is not submitted in one pdf file it will not be accepted.***
* ***A hard copy is not required***
1. **Project Title**

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1. **Principal Investigator**

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**Student Supervisor** (if the Principal Investigator is a student)

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1. **Details of Event**

Date(s) of event:

Sites/locations where the event occurred:

Who was affected by the event?

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| **Party affected** | **Yes** | **No** | **If Yes, provide details** |
| Research Participants – include numbers | [ ]  | [ ]  |       |
| Researcher(s) – provide details of name, role | [ ]  | [ ]  |       |
| Data/records, property, confidentiality or other, please describe | [ ]  | [ ]  |       |

Describe the adverse event using lay language, including any negative consequences, harm or damage that has resulted.

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What is considered the cause of the adverse event?

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Was the event

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| --- | --- | --- |
| [ ]  Related to the project? | [ ]  Possibly related to the project | [ ]  Unrelated to the project? |

|  |  |  |  |
| --- | --- | --- | --- |
|  | NA | Yes | No |
| If the project is a clinical trial, is this classes as a Serious Adverse Event? | [ ]  | [ ]  | [ ]  |
| Is the event considered to have an impact on the ethical acceptability of the research?  | [ ]  | [ ]  |
| Is the incident related to the study design and / or procedure?  | [ ]  | [ ]  |
| Was the adverse event anticipated in the original research protocol?  | [ ]  | [ ]  |
| Was the possibility of this adverse event described in the Participant Information and Consent Form?  | [ ]  | [ ]  |
| Has the participant been withdrawn from the research due to this event? | [ ]  | [ ]  |
| Will the adverse event raise additional safety concerns for the participants of this research or affect participants’ willingness to continue participation? If Yes, provide details below | [ ]  | [ ]  |
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1. **Actions Taken in Response**

Describe the actions taken in response to the adverse event, including both immediate actions to mitigate harm and risk as well as any actions proposed or taken to prevent recurrence.

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Describe the outcome of the actions taken?

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|  | NA | Yes  | No |
| Has the incident been reported to the TGA? | [ ]  | [ ]  | [ ]  |
| Has the incident been reported to the Sponsor? | [ ]  | [ ]  | [ ]  |
| Has the incident been reported to any other bodies? If yes, provide details below | [ ]  | [ ]  |
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| Does the event require: |
| A change to the study design/procedures | [ ]  | [ ]  |
| The submission of an amendment | [ ]  | [ ]  |
| A change to Participant Information Sheet and/or Consent Form | [ ]  | [ ]  |
| Previously enrolled participants to be notified | [ ]  | [ ]  |
| The study to be stopped | [ ]  | [ ]  |

1. **Signatures**

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|  | **Name** | **Signature** | **Date** |
| **Principal Investigator** |       |       |       |
| **Student Supervisor** |       |       |       |
| **Student Supervisor** |       |       |       |