Adverse Report Form **Date:**

You will need to complete this form for any:

• Serious adverse events, including adverse drug reactions;

• Serious unexpected suspected adverse reactions;

• Serious adverse device events; and

• Any other ethical related issue or event that may impact on the continuing ethical approval of this project

Once completed submit the report to the WAAHEC secretariat: ethics@ahcwa.org

# Section 1: Chief Investigator Details

|  |  |
| --- | --- |
| WAAHEC Reference |  |
| Chief Investigator |  |
| Chief Investigator phone |  |
| Chief Investigator organisation |  |
| Chief Investigator email |  |
| Project Title |  |

# Section 2: Participant Details

|  |  |
| --- | --- |
| 1. Date of occurrence |  |
| 2. Location of occurrence |  |
| 3. Has the event or incident been resolved  | Yes | No |
| 4. Who was affected by the event or incident  |
| Person/Product Affected |  |  | If yes, provide further detail such as number of participants/records, names of researcher etc. |
| Research Participants | Yes | No |  |
| Researchers  | Yes | No |  |
| Research Records, Data or Property | Yes | No |  |
| Other | Yes | No |  |

|  |  |  |
| --- | --- | --- |
| 5. Did the event result in or cause any of the following? | Yes | No |
| Death |  |  |
| Life-threatening  |  |  |
| Hospitalisation  |  |  |
| Prolongation of existing hospitalisation  |  |  |
| Persistent or significant disability or incapacity |  |  |
| Congenital anomaly or birth defect |  |  |
| 1. Describe the incident using lay language. Include details of any negative consequences, harm or damage that has occurred because of the incident.
 |  |
| 1. What has been identified as the cause of the incident?
 |  |
| 1. Describe the corrective steps that have occurred and those that are to occur following this report.
 |  |
| 1. Describe the preventative steps to stop reoccurrence.
 |  |
| 1. Has the event/incident had an impact on the ethical acceptability of the research
 |  |
| 1. Was the event/incident related to the study design and / or procedure?
 |  |
| 1. Was the event/incident anticipated in the in the risks section of the approved project description?
 |  |

# Section 3: Reporting

|  |  |  |  |
| --- | --- | --- | --- |
| Has this event been reported to the Sponsor?  | Yes | No | N/A |
| Has this event been reported to the TGA?  | Yes | No | N/A |
| Has this event been reported to the Aboriginal Health Planning Forum | Yes | No | N/A |
| Has this event been reported to the Aboriginal Medical Service | Yes | No | N/A |
| Other, please specify | Yes | No | N/A |
| Was the possibility of this adverse event described in the Participant Information and Consent Form? | Yes | No | N/A |
| Will the adverse event raise additional safety concerns for the participants of this research or affect participants’ willingness to continue participation? | Yes | No |  |
| If yes please provide details |
| Will the adverse event raise additional safety concerns for the participants of this research or affect participants’. In light of the above relationship to the study design and/or procedures what would you recommend? Note: Submit an Amendment form including all amended supporting documentation for the changes proposed below, with this adverse events form. |
| Change to the study design/procedures | Yes | No |
| Change to the Participant Information & Consent Form |  |  |
| Previously enrolled participants to be notified |  |  |
| The study to be stopped |  |  |
| Changes to the study design/procedures |  |  |
| Other Action |  |  |

# Section 4: Certification

DECLARATION: I certify that the information given above is correct to the best of my knowledge. I acknowledge that I must notify the Western Australian Aboriginal Health Ethics Committee if there are any ethically relevant variations.

|  |  |  |  |
| --- | --- | --- | --- |
| Signature of Chief Investigator |  | Dated |  |

Save the completed report and submit electronically to the WAAHEC Secretariat via email ethics@ahcwa.org

# Section 5: Office Use Only

|  |  |  |
| --- | --- | --- |
| Has a similar adverse incident been reported before for the same project?  | Yes | No |
| Has a similar adverse incident been reported before for another approved project? | Yes | No |
| Has this type of adverse event been reported previously at this site or other site for which WAAHEC the lead/responsible HREC? | Yes | No |
| If Yes: Please indicate how often this incident has occurred, the number of participants involved and the outcomes. |
| Follow Up Action |
| WAAHEC Decision |