WAAHEC Western Australian Aboriginal Health Ethics Committee

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

Project title:

HREC Reference number:

Chief Investigator Details

Name:

Contact Number:

Email:

Participant Details

Participant ID:

DOB: *(use dd/mm/yyyy format)* Sex: Female

Participant Condition:
- ☐ Not Recovered
- ☐ Recovering
- ☐ Recovered
- ☐ Unknown

Is the participant continuing in the study:
- ☐ Yes
- ☐ No
- ☐ Not Applicable

Event Details

Description of the event

Event date

Date of recovery

Site of Event

Type of Research – Drug

Type of Event – Other ethical issue or event that may impact on the continuing ethical approval of this project

Level of Severity Mild

Significance of event

- ☐ Resulted in death
- ☐ Life threatening
- ☐ Required hospitalisation
- ☐ Prolonged hospitalisation
- ☐ Congenital / birth defect
- ☐ Other
  Give details

Immediate action taken

Outline the immediate actions taken to mitigate harm and risk

What did you initially consider was the likely cause of the event?

Outline the actions undertaken to reduce risk of recurrence

Consideration of causality of event

For drug studies:
Is there reasonable possibility that the event is related to the study drug or trial intervention? Yes

If yes, provide details on the study drug / intervention name

For non – drug studies:
Is there a reasonable possibility that the event is related to the study procedure or device? Yes

If yes, provide details on the procedure / device name

Do you consider the event to be related to the study project? Yes

If the cause is not known, then what are your current or intended actions to determine the cause?

Changes to research protocol

Was the risk of this event described in the participant information sheet? Yes

Do you believe this event raises any additional safety concerns for participants? Yes

Is a change required to research protocol, the participant information sheet and / or other documentation? Yes

Note: If a modification is required you will need to submit an amendment request form to WAAHEC for consideration prior to implementing any changes

Project monitoring

If applicable, has the study sponsor been notified? Yes

What changes, if any, do you propose to the project monitoring?

Declaration

I / we as the Chief Investigator declare and understand:

- Accept the responsibility for the ethical conduct of this research project
- Undertake to conduct this research project in accordance with the protocols and procedures outlined in the proposal approved by the Western Australian Aboriginal Health Ethics Committee (WAAHEC)
- At the first instance, I need to inform the WAAHEC of any changes to the protocol and submit an Amendment request form;
- Understand and agree study files, documents and records / data may be subject to inspection by approving HRECs for audit and monitoring purposes.

Name Date

Signature

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