

ONCE COMPLETE FAX IMMEDIATELY TO 02476 150 549

DRAFFT—Serious Adverse Event Reporting Form

Centre ID: Participant ID: Participant Initials:

Initial Report Yes No

Follow up report Yes No

Date of Event (dd/mm/yyyy):

Reason for reporting:

- Resulted in death
- Is life threatening
- Required hospitalisation or prolongation of existing hospitalisation
- Resulted in persistent or significant disability or incapacity
- Required medical intervention to prevent one of the above
- Is otherwise considered medically significant by the investigator

Details of event (please give as much information as possible, and if necessary attach a detailed report).
Information must include incident, investigations and treatment given.

Outcome

Ongoing Resolved Resolved with sequelae

In the opinion of the Principal Investigator.....

Is the event related to trial procedure? Yes No

Is the event Expected Unexpected

PI Name:

PI Signature:

Date (dd/mm/yyyy):

In the opinion of the Chief Investigator

Is the event related to trial treatment? Yes No

Is the event Expected Unexpected

CI Signature:

Date (dd/mm/yyyy):