STUDY NUMBER
«CN»-«SN»

OPTIMIST-A TRIAL SERIOUS ADVERSE EVENT FORM

When to complete this form

*This form is to be completed if, in the opinion of the local investigator, a baby enrolled in the OPTIMIST-A trial has experienced an **unexpected serious adverse event (SAE)**.*

*A **serious adverse event** is defined as an untoward medical occurrence that:*

- *Results in death*
- *Is life-threatening*
- *Prolongs hospitalisation*
- *Results in persistent or significant disability or incapacity*
- *Could, in the opinion of the local investigator, become serious if untreated*

NOTE: Many SAEs can occur as part of natural history in the life of a very preterm infant. Only events which in the opinion of the local investigator are **unexpected** are to be reported. Such events should be notified to the OPTIMIST-A Trial Coordinating Centre within one working day of the SAE becoming known to the local investigator, with a **follow-up report** to be completed once the ultimate outcome is known. In addition to completing this form, your local Ethics Committee may require online or hard copy completion of a standard SAE report.

Initial report

Medical record number ☐☐☐☐☐☐☐☐☐☐ (Record no. at study centre) Date of birth ☐☐ DD ☐☐ MM ☐☐☐☐ YYYY

Date of initial report ☐☐ DD ☐☐ MM ☐☐☐☐ YYYY Start date of SAE ☐☐ DD ☐☐ MM ☐☐☐☐ YYYY

Description of the SAE (use back of form if more space needed)

.....

.....

.....

.....

.....

What was the nature of the SAE? (indicate all that apply)

- ○ Unexpected death
- ○ Life-threatening deterioration
- ○ Medical occurrence that will prolong hospitalisation
- ○ Medical occurrence that is likely to result in persistent and significant disability or incapacity
- ○ Medical occurrence that could have become serious if untreated

Relationship of the SAE to the infant's enrolment in the OPTIMIST-A trial

- ○ Unrelated
- ○ Possibly related
- ○ Probably related
- ○ Definitely related

Did the SAE occur at the time of the OPTIMIST-A study intervention? ○ Yes ○ No

*If **yes**, what action was taken?*

.....

.....

.....

Once the initial report is completed, scan or copy the original, retain original in study booklet, and send the initial SAE notification by fax or email (+61 3 62227381; optimist-trials@menzies.utas.edu.au) to the Trial Management Centre (TMC). Send copy of follow-up report when completed. Contact the TMC for additional copies of the SAE form.

Name of person completing this form ..... Signature .....

Description of the SAE

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

Name of person completing this section ..... Signature .....

STUDY NUMBER
«CN»-«SN»

Follow-up report

Date of follow-up report ☐☐ ☐☐ ☐☐☐☐ DD MM YYYY

Outcome of the SAE

○ Recovered

○ Recovered with sequelae

.....
.....
.....
.....
Describe sequelae

○ Died

○ Unknown / other (specify)

.....
.....

Name of person completing this section ..... Signature .....