

DUTY Serious Adverse Event Reporting Form

Secure Fax: 0117 331 3838



Please complete this form using black ink and BLOCK capitals. Options should be selected by placing a cross(X) in the appropriate box.

Once complete please fax to the **Bristol DUTY Study Manager Harriet Downing**, on the above secure fax number, as soon as possible, ideally within 24 hours of the event taking place. **DO NOT SEND THIS FORM TO ANY OTHER DESTINATION.** If you have any questions relating to this form or reporting please ring the DUTY study team on **0117 331 3814** or **3811**.

A serious adverse event is any medical occurrence that results in death, is life-threatening, requires or prolongs hospitalisation, causes persistent or significant disability, results in congenital abnormalities or represents potentially serious harm to research patients and others.

Section 1 – Participant & Site Details

1. Child's Study ID: -
2. Child's Date of Birth:
3. Practice/Site ID:
4. Practice/Site Name:

Section 2 – Adverse Event Details

5. Please provide a description of the serious adverse event:

Use BLOCK capitals (continue on separate sheet if necessary):

6. Date of onset:
7. Has the event resolved: Yes
No
Ongoing
8. Date resolved:

9. If resolved, and the SAE involved admission to hospital, please provide a summary of the discharge diagnosis.

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Section 3 – Type of Event

10. Which serious category did the event match?

(tick one box)

Resulted in death

Life-threatening

Required hospitalisation, or prolongation of existing hospitalisation

Persistent or significant disability /incapacity

Other important medical condition

11. Was the event related to study participation?

Unrelated

Unlikely to be related

Possibly related

Probably related

Definitely related

12. Was the event expected?

Expected

Unexpected

Section 4 – Form Details

13. Date SAE form completed:

14. Signature of person responsible for notification :

15. Please Print Name:

16. Please Print Position:

For [CENTRE] use ONLY

1. Date received:

2. Date entered on database:

3. Entered by:

4. Name of reviewer:

5. Date of review:

6. Comments: