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| Local SUSAR/USADE/URSAE Notification Form |
| To be completed for all clinical trials (therapeutic goods and non-therapeutic goods)This form should be completed by the Principal Investigator (or delegate) as notification to their local Research Governance Office (RGO) when, in the opinion of the investigator[[1]](#footnote-1) one of the following events has occurred at the site:* A *Suspected Unexpected Serious Adverse Event* (SUSAR) in a medicines or biologicals trial
* An *Unanticipated Serious Adverse Device Effect* (USADE) in a medical devices trial
* An *Unexpected and Related Serious Adverse Event* (URSAE) in any other interventional trial

This form should be sent to the RGO within **72 hours** of the site becoming aware of the event. *The investigator should also consider whether the event should be reported locally as an incident (in accordance with PD2014\_004.)* |
| **HREC reference number:** | Click here to enter text. | **Date of this report:** | Click here to enter a date. |
| **Project title:** | Click here to enter text. |
| **Sponsor:** | Click here to enter text. | **Coordinating Principal Investigator:** | Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. | **Department:** | Click here to enter text. |
| **Phone:** | Click here to enter text. |
| Details of the Event |
| **Date event occurred:** | Click here to enter a date. | **Location where the event occurred:** | Click here to enter text. |
| **SSA reference number:** | Click here to enter text. |
| Provide details of the event or attach a copy of the SAE report form.Click here to enter text. |
| In the investigator’s opinion, will the event have any implication for the site that fall outside the management of events in accordance with the protocol?Click here to enter text. |

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| Principal Investigator or Delegate: |
| I declare that the information provided above is true and accurate. |
| **Name of Reporter:** | Click here to enter text. | **Role/Position:** | Click here to enter text. |
| **Telephone:** | Click here to enter text. | **E-mail:** | Click here to enter text. |
| **Signature:** |  | **Date:** | Click here to enter a date. |
| Official Use |
| **Acknowledgement of Receipt: The [RGO Name] acknowledges receipt of the above** |
| **Name:** | Click here to enter text. | **Position:** | Click here to enter text. |
| **Signature:** |  | **Date:** | Click here to enter a date. |

1. New versions will be published on the NSW Health website.

2 For blinded trials, the investigator should not unblind the event for the purposes of reporting to their RGO unless unblinding is necessary for the safety and medical management of the participant. [↑](#footnote-ref-1)