



## **SERIOUS ADVERSE EVENT FORM**

Please complete this form for each serious adverse event and report it within 24 hours to the Principal Investigator, Professor Jane Harding, by sending her a text at 021 515 979 and by emailing a scanned copy of this form to <a href="mailto:j.harding@auckland.ac.nz">j.harding@auckland.ac.nz</a> AND <a href="mailto:hPOD@auckland.ac.nz">hPOD@auckland.ac.nz</a>. If you do not receive a response within 24 hours, forward the form to Dr Carl Kuschel, Chair - Independent Safety Monitoring Committee, at <a href="mailto:Carl.Kuschel@thewomens.org.au">Carl.Kuschel@thewomens.org.au</a>.

Baby's Details			
First Name:			
2. Last Name:			
3. Study number: 1 2	**ATTACH BABY ID STICKER HERE**		
4. Baby's NHI:			
Serious Adverse Event			
5. Serious Adverse Events – Tick one only (Use a separate sheet for each SAE)			
Death – In the event of death please complete as much of the CRF booklet as possible and return it to Liggins.			
Seizure(s) – Please complete additional information on the other side of this form.			
6. Date of event: d d m m 2 0 y y	7. Time of event (24 hr clock): h h m m		
8. Location of event:			
9. Details:			
Full name of person completing this form:	Job title:		
Contact phone number at work:	Mobile number:		
Signature: Please attach this form to the baby's hPOD CRF booklet			

\*\*\* DO NOT FILE THIS FORM WITH THE BABY'S CLINICAL NOTES \*\*\*

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10. Date of seizure:	n m 2 0 y y 11. Time of seizure (24 hr cloc	k): h h m m
12. Seizure:		
12.1 Suspected		
12.2 Confirmed		
Confirmed by CFM / aEEG / Brainz monitor / formal EEG		
13. Blood glucose concentration closest to time of seizure: mmol/L		
14. Date of glucose concentration:	n m 2 0 y y 15. Time of glucose concentration (24 hr cloco	
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16. Treatment with IV dextrose?	Yes No	
17. Underlying cause:	Blood glucose concentration	
	Haemorrhage	
	Meningitis (suspected)	
	Meningitis (confirmed)	
	Hypoxic-ischemic encephalopathy (HIE)	
	Other – specify	

**Seizure Details**