family planning australia
Reproductive & Sexual Health

Serious Adverse Event Reporting Form – *for all clinical trials*

This form should be completed by the Principal Investigator (or delegate) as notification to the approving HREC when, in the opinion of the investigator, a serious adverse event has occurred that is *definitely*, *probably*, or *possibly* related to the trial including but not limited to:

- 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 Ethics Executive Officer within **72 hours** of the site becoming aware of the event.
Please email completed forms to ethics@fpnsw.org.au

Ethics approval number:		**Date of this report:**	**dd/mm/yyyy**
Project title:			
Sponsor:		**Coordinating Principal Investigator:**	
Principal Investigator:		**Unit:**	
		Phone:	

Details of the Event

Date event occurred:	**dd/mm/yyyy**	**Location where the event occurred:**	
Is the SAE *related* to the study?	☐ Definitely ☐ Probably ☐ Possibly	**Was the event expected?**	☐ Yes ☐ No

Please select one of the following:	**Provide details of the event:**
☐ The trial will continue without alteration	
☐ The trial will continue with the PICF having been updated to reflect the amended information	
☐ The trial will continue, however this report raises concerns that the Principal Investigator will monitor and report on as appropriate	
☐ The trial will be suspended	
☐ Other action is required:	

In the investigator's opinion, will the event have any implications for the site that fall outside the management of events in accordance with the protocol? If so, please also complete the Significant Safety Issue (SSI) Notification Form.	☐ Yes ☐ No

Principal Investigator or Delegate

I declare that the information provided above is true and accurate.

Name:		**Role/Position:**	
Telephone:		**E-mail:**	
Signature:		**Date:**	**dd/mm/yyyy**