Significant Safety Issue Notification Form – *for all clinical trials*

Significant safety issues (SSI) that have been implemented as an **urgent safety measure** should be reported within **72 hours** of the sponsor becoming aware of the issue. An urgent safety measure is classified as an action that is required to be taken in order to eliminate an immediate hazard to a participant's health or safety.

All other SSIs should be reported within **15 calendar days** of the sponsor becoming aware of the issue.

This form should be completed and sent to the Ethics Executive Officer within **72 hours** / **15 calendar days** of the sponsor becoming aware of the issue.

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:**	

Details of the Significant Safety Issue

Date event occurred:	**dd/mm/yyyy**

Please provide all relevant details of the SSI:

Actions resulting from the SSI (check all that apply)

☐ **Implementation of an Urgent Safety Measure**

Go to Section 1

☐ **Application to amend approved protocol**

Go to Section 2

☐ **Temporary halt of the trial for safety reasons**

Go to Section 3

☐ **Early termination of the trial for safety reasons**

Go to Section 4

1. Implementation of an Urgent Safety Measure

Please specify the urgent safety measure taken and why it was necessary:

2. Application to amend approved protocol

Is an amendment being submitted with this report?	☐ Yes ☐ No

If no, describe the nature of any planned amendment (e.g. revised protocol or PICF) and the likely timeframe for submission of the Notification of an Amendment to the HREC.

3. Temporary halt of the trial for safety reasons

Please describe the scope of the halt - e.g. suspension of recruitment or cessation/interruption of trial treatment/intervention:

Please provide details of the number of participants still receiving treatment in Australia at the time of the temporary halt and their proposed management:

4. Early termination of the trial for safety reasons

Please provide details of the number of participants still receiving treatment in Australia at the time of early termination and their proposed management:

Please also comment on the consequences of early termination for the evaluation of the study results and provide the anticipated date when the final progress report will be provided to the HREC, if not provided with this notification:

Declaration

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

Reported by (please check one and provide your contact details below):

☐ Sponsor

☐ Sponsor's delegate: Person or organisation authorised by the sponsor

Organisation:		**Contact Name:**	
Telephone:		**E-mail:**	
Signature:		**Date:**	**dd/mm/yyyy**

Please return this form and any attachments to ethics@fpnsw.org.au