Annual/Final Progress Report

Ethics approval is subject to the submission of Annual Progress Reports, which are due at the end of each financial year. When completed, please return this form to the FPNSW Ethics Executive Officer via ethics@fpnsw.org.au.

Reporting period:	YYYY/YYYY		
Project title:			
Ethics approval number:	R#####-##	**Clinical trial registration number:**	
Ethics approval date:		**Ethics expiry date:**	
Principal Investigator:		**Contact person:**	
Have the contact details for the Principal Investigator or contact person changed since the last report?		**Name/Role:**	
		Phone:	
☐ Yes ☐ No *If yes, please provide updated details* ⟶		**Email:**	

Status of project

☐ **Complete**

Please note that a project is considered complete once the data are analysed and a report of the results are written/published.

Date project completed:

Can the file be closed and archived? ☐ Yes ☐ No

Final progress reports should be accompanied by a summary of results and final outcomes

☐ **In progress**

Recruitment completed:

☐ Yes ☐ No ☐ Not applicable

Data collection completed:

☐ Yes ☐ No ☐ Not applicable

Please provide a short summary of progress to date:

☐ **Not yet commenced**

Please provide a statement of explanation:

☐ **Abandoned/discontinued**

Date project abandoned:

Please provide a statement of explanation:

Participants

Has a waiver of consent been granted for this study?	☐ Yes ☐ No ☐ Not applicable

Over the total duration of the project…

What is the total number of participants who are enrolled?	
How many consent forms are available for review?	
Have all participants signed a consent form?	☐ Yes ☐ No ☐ Not applicable
If no, please provide an explanation:	

Since your last report have any participants withdrawn/dropped out?	☐ Yes ☐ No ☐ Not applicable
If yes, please provide the number of participants and reasons for withdrawal/dropout:	

Compliance

Has the project been conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)?	☐ Yes ☐ No
If no, please explain why:	

Has the project been conducted in accordance with the approved protocol?	☐ Yes ☐ No
If no, please explain why permission to amend the protocol was not sought:	

During the last 12 months, have all amendments been submitted to the HREC for approval?	☐ Yes ☐ No
Please note that this includes any changes to project personnel.	*If no*, please attach amendment application

Other

Is data storage in accordance with the approved protocol?	☐ Yes ☐ No
If no, please explain why:	
Have there been any unforeseen events that might affect continued ethical acceptability of the project?	☐ Yes ☐ No
If yes, please describe these events:	
Have there been any publications as a result of this project?	☐ Yes ☐ No
If yes, please list full reference information (including conference presentations, abstracts, journal articles, etc):	

Adverse Events – *for clinical trials only*

Have all Suspected Unexpected Serious Adverse Reactions (SUSARs) and/or Serious Adverse Events (SAEs) been reported to the HREC?	☐ Yes ☐ No ☐ Not applicable
If no, please explain why:	
In accordance with FPNSW Standard Operating Procedure 14, all Serious Adverse Events must be reported to the HREC. Please attach a completed SAE form.	

Authorisation by Principal Investigator

Name:		**Date:**	
Signature:			

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