NOTIFICATION OF COMMENCEMENT OF RESEARCH PROTOCOL

HREC Project Number:

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

This is to advise that the above research protocol commenced on:

/ /

Signature:---------- Date: ---------/----------/----------

Please forward to CHQ HREC:
Amanda Smith, Co-ordinator HREC
Centre for Children's Health Research
Level 7, 62 Graham Street
South Brisbane QLD 4101

Amanda.Smith7@health.qld.gov.au

ANNUAL REPORT FOR RESEARCH PROTOCOLS

HREC PROJECT NO: _____

PROJECT TITLE: _____

PRINCIPAL INVESTIGATOR: _____

	Circle	Date
Has the Project Commenced? (If not, provide approximate date)	**Yes / No**	___/___/___
Has recruitment for the project been completed? (If not, provide approximate date)	**Yes / No**	___/___/___
Has all activity in relation to the project finished at your site? (If not, provide approximate date)	**Yes / No**	___/___/___
Has the Coordinating/Principal Investigator reviewed and reported all Serious Adverse Events to the HREC?	**Yes / No**	___/___/___
Where necessary, have changes been made to the Patient Information and Consent Form, eg additional risks, change of Investigators?	**Yes / No**	___/___/___
Is all trial related data being stored according to ICH Good Clinical Practice as adopted by the TGA?	**Yes / No**	
Have there been any complaints or unfavourable comments from research participants?	**Yes / No**	
If yes, please provide details:		
Has the project been modified in any way? (Includes changes to investigators, PICF, protocol, etc)	**Yes / No**	___/___/___
(If not previously submitted, please provide details of modifications):		
How many participants have been recruited to date?		
Please list any publications that have arisen from this work: (Attach copies)		
Please list any conclusions that have been drawn as a result of this study to date: (Attach a separate sheet if required or interim report)		
Additional Comments:		

Signature of Principal Investigator ..... **Date** ...../...../.....

First Annual Report must be forwarded to HREC 12 months after Ethics approval and every 12 months thereafter to ensure continuing approval for the project.

Children's Health Queensland Human Research Ethics Committee

FINAL REPORT FOR RESEARCH PROTOCOLS

HREC NUMBER: _____

PROJECT TITLE:

_____

RINCIPAL INVESTIGATOR: _____

Number of participants recruited per site(s) *.
Comments: *Notification of closure only after all sites completed
Difficulties encountered during study, if any, eg recruiting.
Comments:
Have there been any complaints or unfavourable comments from research participants? **Yes/No**
Comments:
Have all protocol violations and Serious Adverse Events reported to the HREC and/or Coordinating Principal Investigator? **Yes/No**
Comments:
Were all Serious Adverse Events Reported to the HREC? **Yes / No** **(If not please explain why)**
Comments:
Where, how and for how long is the trial-related data being stored?

Where:	How:	Length of time:

Comments:
Are the final results attached? **Yes / No** **If 'No' when will they be available?**
Comments:
Have results/outcomes been produced/published as appropriate? *Refer to the Australian Code for the Responsible Conduct of Research (Chapter 4)*
Comments:

_____ _____

Signature of Co-ordinating Principal Investigator Date