



**Royal Brisbane & Women's Hospital
Human Research Ethics Committee**

**Metro North
Hospital and Health Service**

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File Ref: HREC/14/QRBW/178
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Dr Glenn J Gardener
Director of Maternal Fetal Medicine
Mater Mothers' Hospital
Level 3 Augibny Place
Raymond Terrace
South Brisbane Q 4101

Dear Dr Gardener,

Re: Ref N^o: HREC/14/QRBW/178: STRIDER (NZAus): A Randomised Controlled Trial of Sildenafil Therapy In Dismal Prognosis Early-Onset Intrauterine Growth Restriction (New Zealand and Australia)

Thank you for submitting the above research project for single ethical review. This project was considered by the Royal Brisbane & Women's Hospital Human Research Ethics Committee (RBWH HREC) (**EC00172**) at its meeting held on 12 May, 2014.

I am pleased to advise that the RBWH Human Research Ethics Committee has granted ethical approval of this research project.

The nominated participating sites for this project are:

- Royal Brisbane & Women's Hospital, Brisbane, Qld
- Mater Mothers' Hospital, Mater Health Services, Brisbane, Qld
- RPA Women and Babies, Royal Prince Alfred Hospital, Sydney, NSW
- Royal Hospital for Women, Sydney, NSW
- The Royal Women's Hospital, Melbourne, Vic
- Women's and Children's Hospital, Adelaide, SA

Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify the RBWH HREC. Notification of withdrawn sites should also be provided to the RBWH HREC in a timely fashion.

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The approved documents include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter		24 April 2014
Application: NEAF (<i>Submission Code: AU/1/7818115</i>)	2.1 (2013)	28 April 2014
Victorian-Specific Module		24 April 2014
Protocol	4	December 2013
Data Sheet - Silvasta		February 2011
CTN Form - Royal Brisbane & Women's Hospital		
CTN Form - Mater Mothers' Hospital, Mater Health Services, Brisbane		
CTN Form - RPA Women and Babies, Royal Prince Alfred Hospital		
CTN Form - Royal Hospital for Women		
CTN Form - The Royal Women's Hospital		
CTN Form – Women's and Children's Hospital		
Health Research Council of NZ (HRC) Funding Letter		29 May 2013
NZ HDEC Ethics initial response letter - conditions for approval		10 July 2012
NZ HDEC Approval Letter		02 October 2012
Subject Medication Diary	1	13 November 2013
Subject Alert Card		
STRIDER materials including magnet, pen, notepad		
Postnatal Questionnaire (main)	1 - NZAus	18 March 2014
Postnatal Questionnaire (baby death)	1 - NZAus	18 March 2014
CRF1: Trial Entry Form	1 - NZAus	27 November 2013
CRF2: Baseline Form	2 - NZAus	26 March 2014
CRF3: Assessment at Randomisation	1 - NZAus	27 November 2013
CRF4: 48 Hours Post-Randomisation	1 - NZAus	27 November 2013

<i>Document</i>	<i>Version</i>	<i>Date</i>
CRF5: Antenatal Maternal/Fetal Assessment	2 - NZAus	April 2014
CRF6: Study Drug Therapy Data	1 - NZAus	27 November 2013
CRF7: Labour & Delivery	1 - NZAus	27 November 2013
CRF8: Maternal Postnatal Outcomes	1 - NZAus	27 November 2013
CRF9: Neonatal Data	1 - NZAus	27 November 2013
CRF10a: Adverse Events	2	March 2014
CRF10b: Serious Adverse Events	1	27 November 2013
CRF12: Withdrawal of Consent	1 - NZAus	27 November 2013
Curriculum Vitae of Glenn Gardener		
Curriculum Vitae of Alec Welsh		
Curriculum Vitae of Emily Olive		
Curriculum Vitae of Peter R Muller		
Curriculum Vitae of Anne Tremellen		
Response to Request for Further Information		27 May 2014
Master Participant Information Sheet & Consent Form	2	21 May 2014
Master Participant Information Sheet & Consent Form - Observational Group	2	21 May 2014
Curriculum Vitae of Renuka Sekar		
Curriculum Vitae of Jonathan Anthony Hyett		
NEAF signature pages		

Approval of this project from the RBWH HREC is valid from **30.05.2014** to **30.05.2017** subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the RBWH HREC of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with the RBWH HREC policy and

procedures. These instructions can be found at
<http://www.health.qld.gov.au/rbwh/research/hrec.asp>.

- In accordance with Section 3.3.22 (b) of the National Statement the Coordinating Principal Investigator will report to the RBWH HREC annually in the specified format, the first report being due on **30.05.2015** and a final report is to be submitted on completion of the study. These instructions can be found at
http://www.health.qld.gov.au/ohmr/html/regu/reporting_templates.asp.
- The Coordinating Principal Investigator will notify the RBWH HREC if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the RBWH HREC of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.
- The Coordinating Principal Investigator will notify the RBWH HREC of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- A copy of this ethical approval letter together with completed Site Specific Assessment (SSA) and any other requirements must be submitted by all site Principal Investigators to the Research Governance Office at each participating institution in a timely manner to enable the institution to authorise the commencement of the project at its site/s.
- Should you have any queries about the RBWH HREC's consideration of your project please contact the HREC Coordinator on 07 3646 5490. The RBWH HREC's Terms of Reference, Standard Operating Procedures, membership and standard forms are available from <http://www.health.qld.gov.au/rbwh/research/hrec.asp>.

The RBWH HREC wishes you every success in your research.

Yours sincerely,



Dr Conor Brophy
Chairperson RBWH Human Research Ethics Committee
Metro North Hospital and Health Service
30.05.2014

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007)*. The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.