



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

File Number: 2010/013135

Attn: CJ Yatawara
c/o Dr Adam Guastella
The University of Sydney BMRI
100 Mallett Street
Camperdown NSW 2050

CTN Scheme (Drugs): Acknowledgement of New Trial – REPLACEMENT LETTER

Your notification to conduct a clinical trial under the Clinical Trial Notification (CTN) Scheme, pursuant to Schedule 5A of Regulation 12 of the Therapeutics Goods Regulations, has been received by the Office of Scientific Evaluation (OSE).

Trial Number: 2010/0413

Protocol Number: 12261

Drug(s):

Drug Active Name	Trade Name	Code Name	Strength
Oxytocin	Syntocinon	OT	12IU

It is noted that:

- i. the approval of the goods for this trial was given in accordance with Item 3 of Schedule 5A of the Therapeutic Goods Regulations by the body or organisation conducting the trial at each additional site.
- ii. the representative of the Ethics Committee for each additional site has certified that the Committee is constituted and operates in accordance with the NHMRC "National Statement on Ethical Conduct in Human Research" has considered this clinical trial, and has provided advice to the body or organisation conducting the trial.

The Therapeutic Goods Administration has not carried out an assessment of the quality, safety or efficacy of any drug product in relation to this notification.

Please note that, in the event that the Secretary of the Commonwealth Department of Health and Ageing becomes aware that to undertake or continue the clinical trial would be contrary to the public interest, the Secretary has the authority to direct that use of the drug product(s) for this clinical trial must cease.

A form "CTN Scheme (Drugs): Trial Completion Advice" is enclosed. Please fill out and return this form after the Clinical Trial has completed.

Heather Davidson
 Experimental Products Section
 Office of Scientific Evaluation
 05 September 2011



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CTN Scheme (Drugs): Clinical Trial Site List

This document lists all sites acknowledged to date for the following clinical trial:

Sponsor: 14195 - University of Sydney

Protocol Number: 12261

Trial Number: 2010/0413

Date Acknowledged	Site Name	State
25 August 2010	University of Sydney, Brain & Mind Institute	NSW



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CTN Scheme (Drugs): Trial Completion Advice

Use this form to notify completion of a trial. Sponsor to complete.

(Notification of completion should be made only after the trial has been completed at all sites. It is not necessary to notify completion dates for individual sites.)

The following Clinical Trial has now been completed:

Sponsor: 14195 - University of Sydney

Protocol No: 12261

Trial Number: 2010/0413

Date Completed:

Completion Reason (Select one only):

Concluded Normally

Premature termination - safety

Insufficient Recruits

Premature termination - other

Directed by HAC Secretary

Other, please state

Print Name

Position

Signature

Phone

Fax

Please mail completed form to:

Therapeutic Goods Administration
P0 Box 100
Woden ACT 2606
Attention: EPS, Office of Scientific Evaluation

Or Fax to (02) 6232 8112