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**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

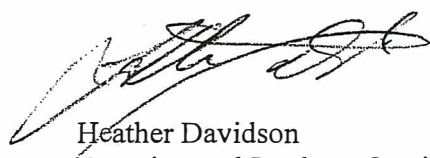
It is noted that:

- 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.
- 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**

<b>Date Acknowledged</b>	<b>Site Name</b>	<b>State</b>
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