



**Australian Government**  
**Department of Health and Ageing**  
**Therapeutic Goods Administration**

File Number: 2011/000965

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**Lidcombe NSW 1825**

**CTN Scheme (Drugs): Acknowledgement of New Trial**

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: 2011/0047  
Protocol Number: 12621

Drug(s):

<b>Drug Active Name</b>	<b>Trade Name</b>	<b>Code Name</b>	<b>Strength</b>
Oxytocin	Syntocinon	OT	24 IU

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.

Sebastian Lavers  
Experimental Products Section  
Office of Scientific Evaluation  
03 February 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: 12621**

**Trial Number: 2011/0047**

<b>Date Acknowledged</b>	<b>Site Name</b>	<b>State</b>
03 February 2011	Brain & Mind Research Institute - University of Sydney	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: 12621

Trial Number: 2011/0047

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