

the children's hospital at Westmea

Research and Development

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12th December 2008

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Corner Hawkesbury Road

Prof Anita Bundy c/- Kim Bulkeley 13 Kyogle Pl GRAYS POINT NSW 2232

Dear Prof Bundy,

HREC reference number:

08/CHW/58

You must quote this number for all future correspondence

Project title:

Reducing negative behavious in daily routines for young

children with autism

NSW Sites listed:

The Children's Hospital at Westmead

Thank you for submitting the above project for single ethical and scientific review. This project was first considered by The Children's Hospital Westmead lead HREC at its meeting held on the 27th June 2008. This HREC has been accredited by the NSW Department of Health as a lead HREC under the model for single ethical and scientific review.

This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*.

I am pleased to advise that the Committee has granted ethical approval of this research project. The documents reviewed and approved include:

Version	Date
1	28 May 2008
2	October 2008
2	September 2008
1	April 2008
1	April 2008
2	October 2008
	April 2008
	April 2008
	1 2

Please note the following conditions of approval:

- 1. The co-ordinating investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including:
 - Unforeseen events that might affect continued ethical acceptability of the project.
- 2. Proposed changes to the research protocol, conduct of the research, or length of HREC approval, will be provided to the HREC for review in the specified format.
- 3. The HREC will be notified, giving reasons, if the project is discontinued at a site before the expected date of completion.
- 4. The co-ordinating investigator will provide an <u>annual</u> report to the HREC and at completion of the study. The annual report form is available on the Hospital's intranet and attached.
- 5. Your approval is valid for 5 years from the date of the final approval letter. If your project extends beyond five years at the 5 year anniversary you are required to resubmit your protocol, according to the latest guidelines, seeking the renewal of your previous approval. In the event of a project **not having commenced** within 12 months of its approval, the approval will lapse and reapplication to the Ethics Committee will be required.

Should you have any queries about the HREC's consideration of your project please contact Ms Eleanor Thackray, Secretary of the Ethics Committee on 9845 3017.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The HREC wishes you every success in your research.

Yours faithfully

Ms Eleanor Thackray

Secretary, Ethics Committee

the children's hospital at Westmead

Research and Development Contact for this correspondence:

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23 December 2008

Professor Anita Bundy University of Sydney PO Box 170 Lidcombe NSW 1825

Dear Professor Bundy,

HREC reference number: 08/CHW/58 SSA reference number: SSA/08/CHW/140

Project title: Reducing negative behaviours in daily routines for young

children with autism

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place here at The Children's Hospital at Westmead.

The following conditions apply to this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval:

- Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are copied to the research governance officer;
- 2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project are to be submitted to the research governance officer.

Yours Sincerely,

Ms Caròlyn Casey

Research Governance Officer

HREC Reference number:	
Project Title (in full):	Reducing negative behaviours in daily routines for young children with autism
Principal Investigator:	Professor Anita C Bundy
This research is:	authorised not authorised
ecify, conditions applying to au	thorisation or reasons for not authorising.
signature indicates that I autho	orise/ do not authorise this research project to commence at this site.
Name of Chief Executive	e (or delegate): Anne O'Neill
Date: 23/12/08	
Signature:	······································



The University of Sydney

Human Research Ethics Committee

Web: http://www.usyd.edu.au/ethics/human

ABN 15 211 513 464

Gail Briody Manager

Office of Ethics Administration

Marietta Coutinho
Deputy Manager

Human Research Ethics Administration

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NSW 2006 AUSTRALIA

Ref: MC/KR

9 March 2009

Professor Anita Bundy Occupational Therapy Faculty of Health Sciences Cumberland Campus – C42 The University of Sydney

Dear Professor Bundy

Title:

Reducing negative behaviours in daily routines for young children with

autism (Ref. No.11677)

PhD Student: Ms Kim M Bulkeley

Your application was reviewed by the Executive Committee of the Human Research Ethics Committee (HREC), and in doing so has ratified your study to include the PhD student – Ms Kim M Bulkeley.

The Executive Committee acknowledges your right to proceed under the authority of *The Children's Hospital at Westmead Ethics Committee*.

Please note, this ratification has been given only in respect of the ethical content of the study.

Any modifications to the study <u>must</u> be approved by *The Children's Hospital at Westmead Ethics Committee* before submission to the University of Sydney Human Research Ethics Committee.

Yours sincerely

Marietta Coutinho

Deputy Manager

CC

Human Research Ethics Administration

Ms Kim M Bulkeley, 13 Kyogle Place, Grays Point NSW 2232