Austin Health

Austin Hospital

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Victoria Australia 3084
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Human Research Ethics Committee
Research Ethics Unit
Henry Buck Building
Austin Hospital

TO: **Dr Larry Abel**
Department of Optometry & Vision Sciences
The University of Melbourne Parkville Vic 3010

PROJECT: Investigating the neurobiological and cognitive features of anorexia nervosa

PROTOCOL NO:
PROJECT NO: H2012/04646

FROM: **Ms Jill Davis, Research Ethics Unit Manager**

DATE: 13 June 2012

RE:

- **Protocol Version 3 dated 22 May 2012**
- **Participant Information and Consent Form Version 3 dated 24 May 2012**
- **Parent Information and Consent form Version 3.1 dated 7 June 2012**
- **Child Assent form Version 3 dated 7 June 2012**
- **MRI pre-scan Information and Consent Form Version 2 dated**
- **MEG pre-scan Information and Consent Form Version dated 18 January 2012**
- **Databank Information and Consent Form Version 6 dated 29 September 2010**
- **Advertisement 2 dated 30 April 2012**
- **Letter of invitation Version 1 dated 1 May 2012**
- **Letter of invitation for parent Version 1 dated 1 May 2012**

Questionnaires:

- **Clinical demographic record**
- **Depression Anxiety Stress Scale (DASS)**
- **Eating Disorders Inventory (EDI-3)**
- **Edinburgh Handedness Inventory**
- **Montgomery Asberg Depression Rating Scale (MADRS)**
- **Mini International Neuropsychiatric Interview (MINI)**
- **Stunkard Figure Rating Scale**
- **Toronto Alexithymia Scale (TAS-20)**
- **Wechsler Test of adult reading (WTAR)**
- **Personality Diagnostic Questionnaire (PDQ-4)**

Approval Period: 13 June 2012 to 13 June 2015

Agenda Item: 6.2

Further to my letter dated 24 May 2012 concerning the above detailed project, I am writing to acknowledge that your response to the issues raised by the Human Research Ethics Committee at their meeting on 17 May 2012 is satisfactory. This project now has full ethical approval for a period of three years from the date of this letter.

Before the study can commence you must ensure that you have:

- For trials involving radiation it is your responsibility to ensure the research is added to the Austin Health Management Licence issued by Department of Human Services – Radiation Safety Section prior to study commencement should it be required (check your Medical Physicist Report). The HREC must be notified when the research has been added to the licence.
- It is a requirement that a progress report is submitted to the Committee annually, or more frequently as directed. Please note a final report must be submitted for all studies. Should you plan for your study to go beyond the 3-year ethics approval, please request in writing an extension of ethics approval prior to its lapsing. If your study will not commence within 12 months, a request must be forwarded to the HREC justifying the delay beyond 12 months. Should such a request not be received, ethics approval will lapse and a resubmission to the HREC will then be necessary.
- After commencement of your study, should the trial be discontinued prematurely you must notify the HREC of this, citing the reason.
- Any changes to the original application will require a submission of a protocol amendment for consideration as this approval only relates to the original application as detailed above.
- Please notify the HREC of any changes to research personnel. All new investigators must be approved prior to performing any study related activities.
- It is now your responsibility to ensure that all people (i.e. all investigators, sponsor and other relevant departments in the hospital) associated with this particular study are made aware of what has been approved.

The Committee wishes to be informed as soon as practicable of any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers. The HREC has adopted the NHMRC Australian Health Ethics Committee (AHEC) Position Statement 'Monitoring and reporting of safety for clinical trials involving therapeutic products' May 2009

Please ensure you frequently refer to the Research Ethics Unit website http://www.austin.org.au/Page.aspx?ID=415 for all up to date information about research and ethical requirements.

DETAILS OF ETHICS COMMITTEE:
It is the policy of the Committee not to release personal details of its members. However I can confirm that at the meeting at which the above project was considered, the Committee fulfilled the requirements of the National Health and Medical Research Council in that it contained men and women encompassing different age groups and included people in the following categories:

Chairperson
Ethicist
Lawyer
Lay Man
Lay Woman
Person fulfilling a Pastoral Care Role
Person with Counselling Experience
Person with Research Experience

Additional members include:

- Chairs of all sub committees, or nominees
- Other persons as considered appropriate for the type/s of research usually being considered

I confirm that the Principal Investigator or Co-Investigators were not involved in the approval of this project. I further confirm that all relevant documentation relating to this study is kept on the premises of Austin Health for more than three years.

The Committee is organised and operates according to the National Statement on Ethical Conduct in Human Research (NHMRC The National Statement) and the Note for Guidance on Good Clinical Research Practice (CPMP/ICH/135/95) annotated with TGA comments (July 2008) and the applicable laws and regulations; and the Health Privacy Principles in The Health Records Act 2001.

PLEASE NOTE: The Committee requests that the Research Ethics Unit ethics@austin.org.au) is informed of the actual starting date of the study as soon as the study commences. A written notice (e-mail, fax or letter) is considered the appropriate format for notification.

Jill Davis
Manager, Research Ethics Unit

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), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice. The process this HREC uses to review multi-centre research proposals has been certified by the NHMRC.

4 June 2012

Dr Larry Abel
Department of Optometry & Vision Sciences
The University of Melbourne
Parkville VIC 3010

Dear Dr Abel,

HREC-A Protocol number: 057/12

'Investigating the neurobiological and cognitive features of Anorexia Nervosa.'

PO Box 2900
Fitzroy Victoria 3065 Australia
Telephone 03 9288 2211
www.svhm.org.au

St. Vincent's Hospital
(Melbourne) Limited
ABN 22 052 110 755
Caritas Christi Hospice Limited
ABN 51 052 110 880
St. George's Health Service Limited
ABN 64 074 683 748
Prague House Limited
ABN 17 066 184 585

The St Vincent's Hospital (Melbourne) Human Research Ethics Committee-A has reviewed and approved the aforementioned study.

Approval Status: FINAL

Period of Approval: 4 June 2012 – 4 June 2016

Ethical approval is given in accordance with the research conforming to the *National Health and Medical Research Council Act 1992* and the *National Statement on Ethical Conduct in Human Research (2007).*

Ethical approval is given for this research project to be conducted at the following sites:

- Body Image Eating Disorders and Recovery Treatment Service (BETRS)
  St Vincent's Hospital (Melbourne)

Approved documents
The following documents have been reviewed and approved:

Document	Version	Date
National Ethics Application Form (NEAF) Module 1	3	28/05/2012
Research Protocol	3	28/05/2012
Participant Information and Consent Form – AN Group	3	28/05/2012
Participant Information and Consent Form – Control Group	3	28/05/2012
Participant Information and Consent Form – for Parents/Guardians (AN Group)	3	28/05/2012
Participant Information and Consent Form – for Parents/Guardians (Control Group)	3	28/05/2012
Participant Information and Consent Form - Carer	3	28/05/2012
Advertisement	2	22/05/2012

St Vincent's
Continuing the Mission of the Sisters of Charity

St Vincent's HREC-A Protocol number: HREC-A 057/12
Please quote these numbers on all Correspondence

Approval is subject to:

- The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research (2007).
- Immediate notification to the Research Governance Unit of any serious adverse events on participants.
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- Notification of proposed amendments to the study;
- Submission of an annual report, due on the anniversary date of approval, for the duration of the study.
- Submission of reviewing HREC approval for any proposed modifications to the project;
- Submission of a final report and papers published on completion of project;
- Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

Please note: Any Serious Adverse Events (SAEs) relating to patient information and/or data management must reported to HREC-A within 24 hours (*for information only*).

The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

Ms Anita Arndt
Senior Administrative Officer and HREC-A Secretary
Research Governance Unit
St Vincent's Hospital (Melbourne)

To: Prof Susan Rossell, BPsyC, FLSS

Dear Susan

SUHREC Project 2012/277 Investigating the neurobiological and cognitive features of Anorexia Nervosa

Prof Susan Rossell, BPsyC/FLSS et al

(UofMelb CI: Dr Larry Abel; Student: Ms Andrea Phillipou. SVH HREC-A Protocol 057/12)

Approved Duration to 01/05/2015 [Adjusted]

I refer to the application for Swinburne ethics clearance for Swinburne involvement in the above collaborative project involving St Vincent's Hospital, Melbourne and the University of Melbourne and given ethics clearance by St Vincent's Hospital Human Research Ethics Committee (SVH HREC-A) (Protocol 057/12).

Relevant documentation pertaining to the application was emailed by you on 20 November 2012 with attachments, then a full set of updated and additional information forwarded on your behalf by Ms Andrea Phillipou in two emails on 19 December 2012. The original documentation was given expedited ethical review by a delegate of Swinburne's Human Research Ethics Committee (SUHREC) significantly on the basis of the prior SVH HREC-A ethical review and a recommendation to approve given on the basis of further clarification/information needed as now contained in Ms Phillipou's emails of 19 December 2012.

I am pleased to advise that, as submitted to date, Swinburne ethics clearance has been given in line with standard on-going ethics clearance conditions here outlined (as applicable) and on the understanding that appropriate insurance arrangements are in place to cover the Swinburne-sanctioned research activity. (Nb SVH HREC-A may need to be apprised of the Swinburne ethics clearance.)

- All human research activity undertaken under Swinburne auspices must conform to Swinburne and external regulatory standards, including the current *National Statement on Ethical Conduct in Human Research* and with respect to secure data use, retention and disposal.
- The named Swinburne Chief Investigator/Supervisor remains responsible for any personnel appointed to or associated with the project being made aware of ethics clearance conditions, including research and consent procedures or instruments approved. Any change in chief investigator/supervisor requires timely notification and SUHREC endorsement.
- The above project has been approved as submitted for ethical review by or on behalf of SUHREC. Amendments to approved procedures or instruments ordinarily require prior ethical appraisal/ clearance. SUHREC must be notified immediately or as soon as possible thereafter of (a) any serious or unexpected adverse effects on participants and any redress measures; (b) proposed changes in protocols; and (c) unforeseen events which might affect continued ethical acceptability of the project.
- At a minimum, an annual report on the progress of the project is required as well as at the conclusion (or abandonment) of the project. (A copy of any progress, annual or final report submitted to SVH also being submitted to my office should meet these requirements, all things being equal; similarly with any request to modify the approved protocol.)
- A duly authorised external or internal audit of the project may be undertaken at any time.

Please contact me if you have any queries about Swinburne on-going ethics clearance and if you need a signed Swinburne ethics clearance certificate, citing the SUHREC project number. Copies of clearance emails should be retained as part of project record-keeping.

Best wishes for the project, including for Ms Phillipou's research.

Yours sincerely

Keith

Keith Wilkins
Secretary, SUHREC & Research Ethics Officer
Swinburne Research (H68)
Swinburne University of Technology
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The Melbourne Clinic

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A Healthscope Hospital

Dr Larry Abel
Department of Optometry & Vision Sciences
The University of Melbourne
PARKVILLE 3010
11 December 2013

Dear Dr Abel

Re Project 235: Investigating the neurobiological and cognitive features of Anorexia Nervosa.

I confirm that at the meeting of The Melbourne Clinic Research Ethics Committee held on the 11 December 2013 your letter dated 22 Nov 2013 and the following study documents:

1. TMC Application Form
2. Research Proposal (Version 1. Dated 22 November 2013)
3. Investigators Relationship to the Research
4. Scales to be used in the study:
    - MCCB Administrators Form and Respondents Booklet
    - Attachment Style Questionnaire
    - Barratt Impulsiveness Scale (BIS-11)
    - Demographic Record
    - DASS 42
    - EDE-Q
    - Edinburgh Handedness Questionnaire
    - Figure Rating Scale
    - Intolerance of Uncertainty Scale
    - MADRS
    - M.I.N.I
    - Need Threat Scale
    - Personality Diagnostic Questionnaire (PDQ-4)
    - Sensitivity to punishment and reward questionnaire
    - Social Anhedonia Questionnaire (revised)
    - Toronto Alexithymia Scale (TAS-20)
    - Wechsler Test of Adult Reading (WTAR).
5. Patient Information sheet (Version 1. Dated 22 November 2013)
6. Patient Consent Form (Version_ not dated)
7. MEG Pre-Scan Information, Checklist and Consent Form for Participants (Version _ dated 18.01.2012)
8. MRI-15 checklist and Consent Form for Participants no contrast (Version 2, not dated)
9. TMC Consultants Permission Form
10. Cognitive and Genetic Explanations of Mental Illnesses (CAGEMIS) Bio-Databank PICF (Version 9, dated 30.4.12)
11. Advertising Flyer
12. CV of the PI
13. Letter of Approval from other HRECS
    1. Austin Health (dated 13 June 2012)
    2. Austin Health amendment to the Protocol, PICF & advertisement (dated 25 Sept 2012)
    3. Austin Health amendment to the Letter of Invitation (dated 26 Sept 2012)
    4. Austin Health amendment to the Protocol (dated 28 Sept 2012)
    5. Austin Health amendment to the Protocol, PICF, advertisement (dated 21 Dec 2012)
    6. Austin Health amendment to the Protocol & addition of a scale (dated 16 April 2013)
    7. Letter of Acknowledgement of St Vincent's HREC approval from the HREC of the University of Melbourne (dated 24 Jan 2013)

8. Letter of Acknowledgement of St Vincent's HREC approval from the HREC of the Swinburne ethics (undated)
9. St Vincent's - final Approval (dated 4 June 2012)
10. St Vincent's - amendments to the Protocol, PICF and reimbursement (dated 27 August 2012)
11. St Vincent's - amendment to the advertisement (dated 28 August 2012)
12. St Vincent's - amendment to the Protocol (dated 15 October 2012)
13. St Vincent's - amendment to the Protocol, eye movement tasks, scales, patient reimbursements and study personnel (dated 11 Dec 2012)
14. St Vincent's - addition of letter of invitation (dated 21 Jan 2013)
15. St Vincent's - amendment to the Protocol (dated 24 April 2013)
16. St Vincent's - amendment to the advertisement (dated 2 July 2013)

Were tabled, discussed and approved with the proviso that in the PICF (Version 1. dated 22.11.13) first paragraph under point 1. Introduction; there is a fuller explanation to patients, in particular with regards to "different strategies" and "certain tasks."

Enclosed is the "Acceptance of Researchers Requirements Form." The Acceptance of Research Requirements Form outlines the terms and conditions of The Melbourne Clinics Research Ethics Committees approval of your project. Please sign and return this form to the Secretariat as soon as possible.

I confirm for the record that although we do not list Committee members by name that the Committee is constituted and functions in accordance with the National Statement on Ethical Conduct in Research Involving Humans (2007) issued by the National Health and Medical Research Council (NHMRC) in accordance with the NHMRC Act, 1992.

We wish you success with the research and look forward to hearing from you further on its progress.

Yours sincerely

Dr Harry Derham
Chair
Research Ethics Committee

The Melbourne Clinic
130 Church Street
Richmond VIC 3121

The Melbourne Clinic

ACCEPTANCE OF RESEARCH REQUIREMENTS

I/we agree to abide by the guidelines and conditions for the conduct of research as laid down in this document, The Melbourne Clinic Research Ethics (TMC REC) "Conditions and Guidelines" document and in the Letter of Approval from the Chairman of the Committee.

Specifically; I/We agree to the following:

- To conduct the study in accordance with the NHMRC National Statement on Ethics Conduct in Human Research (2007) and as a basic standard comply with the Australian Code for the Responsible Conduct of Research (2007) and the ICH Guidelines for Good Clinical Practice (GCP).

- To notify the TMC REC of any significant changes or amendments to the project, the reason for those changes including changes to study personnel and the PI contact details.

- To notify the TMC REC of any Serious Adverse Events and the action taken to address the event or events.

- To provide an Annual Report of the projects progress when requested by the secretariat.

- To notify the TMC REC of the termination of the project or any significant delay in commencing the project.

TITLE OF THE RESEARCH PROPOSAL: Project 235: **Investigating the neurobiological and cognitive features of Anorexia Nervosa.**
NAME OF THE RESEARCHER/S: Dr Larry Abel.
NAME (Please print): LARRY ABEL ..... SIGNED: ..... DATE: 06/01/2014.....

THE UNIVERSITY OF MELBOURNE

24 January 2013

Dr L.A. Abel
Optometry and Vision Sciences
The University of Melbourne

Dear Dr Abel

I am writing to advise you that this project has been registered at this University as approved by St Vincent's HREC which is the Responsible Human Research Ethics Committee for this project. Please take note of the University ethics ID Number below.

Project title:	**Investigating the neurobiological and cognitive features of anorexia nervosa**
Researchers:	**Dr L A Abel, A Phillipou, Dr C Keating, Professor D J Castle, Associate Professor R Newton, Mr R Nibbs, Dr W Woods, Miss R Batty, Professor S Rossell**
Ethics ID:	**1239068**

Please note the following conditions of registration:

1. The St Vincent's HREC approval must be current for the life of the project.
2. You are required to keep the Health Sciences Human Ethics Sub-Committee informed of any subsequent variations or modifications made to the project and any such changes must be approved by St Vincent's HREC.
3. You are required to submit an annual report to the Human Research Ethics Committee at the end of each year, or at the conclusion of the project if it continues for less than this time. Requests for annual reports will be sent out via Themis.

Yours sincerely

Ms Kate Murphy
Executive Officer, Human Research Ethics
Phone: 83442073, Email: k.murphy@unimelb.edu.au

cc: Head, Optometry and Vision Sciences
Andrea Phillipou