St Vincent's Hospital

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24 November 2016

Prof Gavin Andrews
CRUfAD
Level 4 O'Brien Centre
Darlinghurst NSW 2010

Dear Gavin,

SVH File Number: 16/096
Project Title: A pilot trial of the iCanADAPT Advanced Program, an Internet Cognitive Behavioural Therapy (iCBT) program for the treatment of depression and anxiety in ambulatory advanced-stage cancer patients.
Short Title: iCan ADAPT Advanced Program Pilot
HREC Reference Number: HREC/16/SVH/147
SSA reference: SSA/16/SVH/264

Thank you for submitting an application for authorisation of this project. I am pleased to advise that the Director of Research, on **23 November 016**, has granted site authorisation for the above project to commence at

- **St Vincent's Hospital, Sydney**

Documents to be used at this site are:

- iCanADAPT Advanced Participant Information Sheet and Consent Form, Version 2, dated 29 July 2016
- iCanADAPT Advanced SVH Flyer, Version 2, dated 1 August 2016
- Protocol, Version 3, dated 12 September 2016

The SSA form reviewed was: **AU/2/98F8212**

Site authorisation will cease on the date of HREC expiry (**16 August 2021**).

NOTE RE HONORARY APPOINTMENT: Amy Joubert cannot commence study related responsibilities at the approved site until all SVH Human Resources requirements have been met which includes an Honorary Appointment/s. An Honorary Appointment document pack is attached which contains the relevant forms necessary to process an Honorary Appointment. Please note that it is the responsibility of the individual researcher and the Principal Investigator of the study to organize and submit all the appropriate and relevant paperwork to Ms Christine Blake (c.blake@amr.org.au) to finalise the Honorary Appointment/s.

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:

1. The Principal Investigator must provide the St Vincent's Hospital Research Governance Officer via email (SVHS.Research@svha.org.au) with the following OHMR/MoH imposed Metrics:
   - Within 45 calendar days of the date that the delegate of the institution has granted site authorisation for this project, report the date on which the first participant was enrolled to the clinical trial by this site. If at least one participant was not enrolled within 40 calendar days, a reason for the delay in enrolment also must be reported to the Research Governance Officer.
   - Within 15 days of site closure to enrolment, report the total number of participants enrolled in the clinical trial at the above site and report whether the minimum enrolment

target as per the CTRA was reached. If the enrolment target was not reached, provide an explanation.

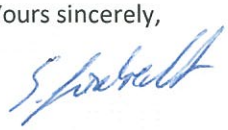
2. An annual progress report will be provided to the Research Governance Officer acknowledged by the LEAD HREC beginning in **August 2017.**
3. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and are submitted to the lead HREC for review, are copied to the Research Governance Officer prior to implementation of the amendment on site.
4. All 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 via email to the Research Governance Officer for review.
5. The relevant University HREC may require notification for projects that are undertaken by investigators holding an academic appointment (including conjoint appointments) or by students as part of a University course. This is the responsibility of the investigators.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries about your project please contact the Research Office, Ph 8382 4960, email SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website to be found at: https://svhs.org.au/home/research-education/research-office

Please quote **SVH file reference 16/096** and **HREC reference HREC/16/SVH/147** in all correspondences.
The SVH Research Office wishes you every success in your research.

Yours sincerely,



Dr Sabine Giesebrecht
Research Governance Officer
St Vincent's Hospital Research Office
Translational Research Centre, 97-105 Boundary Street

Cc: Michael Murphy
TRIM REF: D/2016/109987