



**ST VINCENT'S
HOSPITAL**
SYDNEY

A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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12 May 2017

Prof Gavin Andrews
Clinical Research Unit for Anxiety and Depression
Level 4, O'Brien Centre
St Vincent's Hospital
Darlinghurst NSW 2010

Dear Gavin,

SVH File Number: 17/054

Project Title: A Randomised Controlled Trial (RCT) of LivingWELL+, an internet Cognitive Behavioural Therapy (iCBT) program for the treatment of depression and anxiety in men who have sex with men (MSM) who are living with HIV

Short Title: LivingWELL + HIV

HREC Reference Number: HREC/17/SVH/74

Thank you for your letter, dated **21 April 2017**, responding to issues raised regarding the above project, which was first considered by the St Vincent's Hospital HREC at its meeting held on **9 March 2017**.

This project meets the requirements of the National Statement on Ethical Conduct in Human Research. I am pleased to advise that the Committee at an Executive meeting on **9 May 2017** has granted ethical and scientific approval of the above **single centre** project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note that it is not considered best practice to store research data on personal hardware. No identifiable participant data can leave a site. There always needs to be data security measures in place and a clear plan for permanent destruction of data needs to be adhered to at completion of the project.

The project is approved to be conducted at:

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

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

- Protocol LivingWELL, Version 2 dated 21 April 2017

- FAHI Questionnaire, Version 4 dated 19 November 2007
- LivingWELL Participant Information Sheet and Consent Form, Version 2 dated 11 April 2017
- Poster Recruitment Ad_TWUHIV_RCT, Version 3 dated 21 April 2017

The National Ethics Application Form (NEAF) document reviewed by the HREC was NEAF **AU/1/4DOC218**.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **9 May 2022**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an annual progress report beginning in **May 2018**, to the HREC as well as a final study report at the completion of the project in the specified format.
- 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 and any complaints made by study participants regarding the conduct of the study.
- 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.
- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg. Australian Clinical Trial Registry <http://www.anzctr.org.au/> and <https://clinicaltrials.gov/>).

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 regarding this project please contact the Research Office, Tel: 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: <https://svhs.org.au/home/research-education/research-office>

St Vincent's Hospital HREC (EC00140) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

Please quote **SVH File Number: 17/054** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'S. Charlton', with a long horizontal flourish extending to the right.

Sarah Charlton
HREC Executive Officer
St Vincent's Hospital Research Office
Translational Research Centre, 97-105 Boundary Street

cc: Michael Millard
TRIM REF: D/2017/48417