Government of South Australia
SA Health

Human Research Ethics Committee (TQEH/LMH/MH)
Basil Hetzel Institute DX465101
The Queen Elizabeth Hospital
28 Woodville Road
Woodville South SA 5011
Telephone: 82226841

04 June 2015

Dr Phillip Tully
Cardiology Department
The Queen Elizabeth Hospital
28 Woodville Road
Woodville South SA 5011

Dear Dr Tully

HREC reference number: HREC/15/TQEH/47
Project title: Cardiovascular Health in Anxiety or Mood Problems (CHAMP): A randomized controlled trial of transdiagnostic treatment of emotional disorders among cardiac patients

RE: Ethics Application Approval

Thank you for submitting additional information received on 26 May 2015 in relation to the above project for ethical and scientific review.

We have reviewed your response, and I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research, incorporating all updates*. The documents reviewed and approved include:

Document	*Version*	*Date*
NEAF Proposal for research	AU/1/B8CD113	19 March 2015
Covering Letter	-	19 March 2015
Response to HREC Chairman's request for further information, pre HREC meeting	-	06 April 2015
Response to Request for Further Information	-	27 April 2015
Response to Request for Further Information	-	19 May 2015
Protocol	5	27 April 2015
Master Participant Information Sheet: Main	TQEH v4	28 May 2015
Participant Study Withdrawal Sheet	-	27 April 2015
CHAMPS Questionnaire Battery_PREPOSTFOLLOWUP	-	27 April 2015
CHAMPS high scores at follow-up letter	-	15 March 2015
Routine Questionnaire Battery PHQ, GAD, SF-12	-	18 February 2015
CHAMPS Questionnaire Battery_SCREENING	-	18 February 2015

Sites covered by this approval:

- **The Queen Elizabeth Hospital, SA**

HREC approval is valid from **04 June 2015 to 04 June 2018.**

Please note that approvals are subject to annual review reports submitted every 12 months from the date of approval. Failure to submit reports may result in the HREC revoking its approval.

The responsibility of submitting an annual review reporting is with the Coordinating Principal investigator.

Please note the following conditions of approval:

1. This HREC will act as the South Australian 'lead HREC' for the purpose of this ethics approval. Any study sites that are not listed on this letter are not covered by this ethics approval. Any SA study-sites within the public health system that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site and a separate formal letter will be issued.
2. Annual review reports must be submitted to the HREC, every 12-months from the date of approval. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal investigator to ensure this is carried out.
3. Researchers are required to immediately report to this HREC anything which might warrant review of ethical approval of the study, including:
    a. serious or unexpected adverse effects on participants;
    b. proposed changes in the study; and
    c. unforseen events that might affect continued ethical acceptability of the project.
4. Confidentiality of the research subjects shall be maintained at all times as required by law.
5. All research subjects shall be provided with a Participant Information Sheet and Consent Form, unless otherwise approved by the HREC.
6. Adequate record-keeping must be maintained in accordance with GCP, NHMRC and state and national guidelines. The duration of record retention for all clinical research data is 15 years from the date of publication.
7. SA Health requires all institutions under its jurisdiction to dispose of research materials in accordance with the requirements outlined in the NHMRC Australian Code for the Responsible Conduct of Research.
8. A report and a copy of any published material should be forwarded to the HREC at the completion of the project.

This Committee is constituted in accordance with the NHMRC *National Statement on the Ethical Conduct of Human Research (2007) and incorporating all updates.*

You are reminded that this letter constitutes ethical approval only. You cannot commence this project until you receive site authorisation from the CEO or delegate, even if ethics approval is received.
To obtain site authorisation, a separate Site Specific Assessment (SSA) application should be made to each public health site involved in the study, through the Site's Research Governance Officer. For more information, please visit:
http://www.basilhetzelinstitute.com.au/research/research-ethics-governance/governance-site-specific-assessments-ssa-

If University personnel are involved in this project, the Principal Investigator should notify the University before commencing their research to ensure compliance with University requirements including any insurance and indemnification requirements.

Should you have any queries about the HREC's consideration of your project please the HREC Executive Officer on 08 8222 6910 or qeh.ethics@health.sa.gov.au

The HREC wishes you every success in your research.

Yours sincerely

Professor Richard E Ruffin
Chairman, Human Research Ethics Committee (TQEH/LMH/MH)
RR:CC

cc: Site Research Governance Officer(s) CALHN