



3 August 2017

Ms Amily Daw & Ms Anna Francis
Northern Clinical Psychosocial Rehabilitation Program 'Club84'
Northern Adelaide Local Health Network

Dear Ms Daw & Ms Francis,

Project title: A 12 week pilot study targeted for adult consumers within a community mental health rehabilitation setting to implement a Personal Safety Tool for self-management and crisis management.

HREC reference number: HREC/17/TQEH/132

CALHN reference number: Q20170609

RE: Ethics Application APPROVAL

Thank you for submitting the above project for ethical and scientific review. The project was first considered by The Queen Elizabeth Hospital Human Research Ethics Committee (TQEH/LMH/MH) at its meeting held on 10 July 2017.

The HREC has reviewed all responses, 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
HREA Form	AD02737	1 June 2017
Cover Letter	-	19 June 2017
Project Description	1	1 August 2017
Participant Information Sheet and Consent Form	1	1 August 2017
Post Project Study Questionnaire	1	1 August 2017
Pre Project Study Questionnaire	1	1 August 2017
Weekly Questionnaire	1	1 August 2017

Sites covered by this approval:

- **Northern Adelaide Local Health Network, SA: PI – Ms Amily Daw & Ms Anna Francis**

HREC approval is valid for **5 years** from **3 August 2017 to 3 August 2022**.

Please quote the **HREC Reference number, HREC/17/TQEH/132** and the **CALHN Reference number, Q20170609** allocated to your study on all future correspondence.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

1. For all clinical trials, the study must be registered in a publicly accessible trials registry prior to enrolment of the first participant.
2. This HREC is certified with the NHMRC for National Mutual Acceptance of Single Ethical and Scientific Review of Multi-Centre Clinical Trials. Any study sites that are not listed on this letter are not covered by this ethics approval. Any study-sites that wish to be added must contact the CPI, who must write formally to this HREC requesting the additional study site.
3. Adequate record-keeping is important and must be maintained in accordance with GCP, NHMRC and state and national guidelines. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.

4. Researchers must notify the HREC of anything which might warrant review of the approval of the study, or which warrant new information being presented to research participants, including:
 - (a) adverse events which warrant protocol change or notification to research participants;
 - (b) changes to the protocol;
 - (c) changes to the safety or efficacy of the investigational product, device or method;
 - (d) premature termination of the study.
5. The Committee must be notified within 72 hours of any Urgent Safety Measures (USMs) occurring at this or any approved sites.
6. Confidentiality of the research participants shall be maintained at all times as required by law.
7. Approval is valid for **5 years** from the date of this letter, after which an extension must be applied for.
8. Annual review reports must be submitted to the HREC, every 12-months on the anniversary of the above approval date. Each site covered by this HREC must submit a report, and it is the responsibility of the Coordinating Principal Investigator to ensure this is provided to the TQEH HREC Executive Officer, within 10 working days on each anniversary of the approval date, using the Annual Review Form available at: <http://www.basilhetzelinstitute.com.au/research/information-for-researchers/human-research-ethics-committee/>
9. The HREC must be advised with a final report or in writing, and a copy of any published material within 30 days of completion of the project.

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at any site until separate authorisation from the Chief Executive or delegate of that site has been obtained. For any queries, please contact the CALHN Governance Office:
Health.CALHNResearchGovernance@sa.gov.au

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

Should you have any queries about the HREC's consideration of your project, please contact Mrs Heather O'Dea, HREC Executive Officer on 08 8222 6841 or Health.CALHNResearchEthics@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:HO