Office for Research

Flinders Medical Centre
Ward 6C, Room 6A219
Flinders Drive, Bedford Park SA 5042
Tel: (08) 8204 6453
E: Health.SALHNOfficeforResearch@sa.gov.au

Government of South Australia
SA Health
Southern Adelaide Local Health Network

Final approval for ethics application

You are reminded that this letter constitutes **ethical** approval only. **Ethics approval is one aspect of the research governance process.**
You must not commence this research project at any SA Health sites listed in the application until a Site Specific Assessment (SSA), or Access Request for data or tissue form has been authorised by the Chief Executive or delegate of each site.

30 November 2016

A/Professor Lily Xiao
School of Nursing and Midwifery
Flinders University
BEDFORD PARK SA 5042

Dear A/Professor Xiao

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided ethical approval for this application which appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research.*

Application Number: OFR # 345.16 - HREC/16/SAC/308

Title: Hypertension management program for community-dwelling older people with diabetes in Nanchang, China: a cluster randomised controlled trial

Chief investigator: A/Professor Lily Xiao

Approval Period: 30 November 2016 to 30 November 2019

The below documents have been reviewed and approved:

- General Research Application v.1.0 dated 26 August 2016
- PICF Intervention Group v1.0 13 dated August 2016
- PICF Usual Care Group PICF Intervention Group v1.0 13 dated August 2016
- Intervention Protocol v1.0 dated 16 August 2016
- Health Knowledge Questionnaire v1.0 dated 16 August 2016
- Intervention Diary Patient v1.0 dated 16 August 2016
- Intervention Record Community Nurse & GP v1.0 dated 16 August 2016
- Recruitment Posters & Response Slips v1.0 dated 16 August 2016
- Email Text Health Professionals Pilot v1.0 dated 16 August 2016
- Letter of Introduction v1.0 dated 25 August 2016.pdf

The following documents have been noted:

- SBREC Approval dated 5 February 2016
- Fulmer Spices Comprehensive Assessment Tool Older Adults v1.0 dated 16 August 2016
- Usual Care Table v1.0 dated 16 August 2016
- Chinese Versions
    - Chinese version Appendices
    - Chinese version Hypertension Knowledge Level Scale (HK-LS)

TERMS AND CONDITIONS OF ETHICAL APPROVAL
As part of the Institution's responsibilities in monitoring research and complying with audit requirements, it is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5.*

Final ethical approval is granted subject to the researcher agreeing to meet the following terms and conditions:

1. The approval only covers the science and ethics component of the application. A SSA will need to be submitted and authorised before this research project can commence at any of the approved sites identified in the application.
2. 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.
3. Compliance with the *National Statement on Ethical Conduct in Human Research* (2007) & the *Australian Code for the Responsible Conduct of Research* (2007).
4. To immediately report to SAC HREC anything that may change the ethical or scientific integrity of the project.
5. Report Significant Adverse events (SAE's) as per SAE requirements available at our website.
6. Submit an annual report on each anniversary of the date of final approval and in the correct template from the SAC HREC website.
7. Confidentiality of research participants MUST be maintained at all times.
8. A copy of the signed consent form must be given to the participant unless the project is an audit.
9. Any reports or publications derived from the research should be submitted to the Committee at the completion of the project.
10. All requests for access to medical records at any SALHN site must be accompanied by this approval email.
11. To regularly review the SAC HREC website and comply with all submission requirements, as they change from time to time.
12. Once your research project has concluded, any new product/procedure/intervention cannot be conducted in the SALHN as standard practice without the approval of the SALHN New Medical Products and Standardisation Committee or the SALHN New Health Technology and Clinical Practice Innovation Committee (as applicable) Please refer to the relevant committee link on the SALHN intranet for further information.

Kind Regards

A/Professor Bernadette Richards
Chair, SAC HREC