

Office for Research

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Government of South Australia

SA Health

Southern Adelaide Local Health Network

Final Approval for Ethics Application

5 March 2018

Professor Richard Reed
Professor of General Practice
Flinders University
GPO Box 2100
Adelaide
SA 5001

Dear Professor Reed

OFR Number: 313.17
Project title: Do enhanced general practices services improve health outcomes and health service use? Flinders Quality Enhanced general practice Services Trial (Flinders QUEST)
Chief Investigator: Professor Richard Reed
Ethics Approval Period: 23rd February 2018 – 23rd February 2021

The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC EC00188) have reviewed and provided approval for this application which meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*.

You are reminded that this letter constitutes **Ethics** 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 approved by the Chief Executive or delegate of each site.

The below documents have been reviewed and approved:

- Letter of response to Ethics 11/01/2018
- Letter of response to SAC HREC 14/02/2018
- HREA 11/01/2018
- Flinders Quest Protocol v3 14/02/2018
- GP handout v1 21/11/2017
- Letter to participants v2 12/01/2018
- Letters of invitation v2 12/01/2018
- Parent Baseline Questionnaire v3 14/02/2018
- Parent Consent Form v3 14/02/2018
- Parent Demographics v1 12/01/2018
- Parent Information Sheet v3 14/02/2018

- Parent Medicare Consent v1 21/11/2017
- Parent Sixth Month Questionnaire v3 14/02/2018
- Parent Twelve Month Questionnaire v3 14/02/2018
- Parent Twelve Month Intervention Questionnaire v3 14/02/2018
- Participant Baseline Questionnaire v3 14/02/2018
- Participant Consent Form v2 12/01/2018
- Participant Demographics v1 12/01/2018
- Participant Information Sheet v3 14/02/2018
- Participant Medicare Consent v2 12/01/2018
- Participant Six Month Questionnaire v3 14/02/2018
- Participant Twelve Month Intervention Questionnaire v3 14/02/2018
- Participant Twelve Month Questionnaire v3 14/02/2018
- Redcap Screenshot 12/01/2018
- Young Person Baseline Questionnaire v3 14/02/2018
- Young Person Demographics v1 12/01/2018
- Young Person Six Month Questionnaire v3 14/02/2018
- Young Person Twelve Month Intervention Questionnaire v3 14/02/2018
- Young Person Twelve Month Questionnaire v3 14/02/2018
- Letter of support to SAC HREC (signed Bill Heddle) 26/10/2017
- AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research Toolkit September 2009

The below documents are noted by SAC HREC

- Memorandum of Insurance Group Personal Accident 31/10/2017
- Memorandum of Insurance Medical Malpractice 31/10/2017
- Memorandum of Insurance Professional Indemnity 31/10/2017
- Memorandum of Insurance Public and Product Liability 31/10/2017

Terms and Conditions Of Ethics Approval:

It is essential that researchers adhere to the conditions below and with the *National Statement chapter 5.5*.

Final ethics 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 ethics 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.

For any queries about this matter, please contact The Office for Research on (08) 8204 6453 or via email to Health.SALHNOfficeforResearch@sa.gov.au

Yours sincerely



A/Professor Bernadette Richards
Chair, SAC HREC