



A/Professor Judy Katznellenbogen
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Dear A/Professor Katznellenbogen

HREC reference number: HREC/16/SAH/120

Project title: Baseline for monitoring the burden of rheumatic heart disease in Australian jurisdictions: South Australia component

RE: HREC Application – Approval

Thank you for submitting the above project, which was considered by the SA Department for Health and Ageing Human Research Ethics Committee (DHA HREC) at its meeting on December 6th, 2016.

I am pleased to advise that your application has been granted full ethics approval, including a Waiver of Consent, and appears to meet the requirements of the *National Statement on Ethical Conduct in Human Research*.

The documents reviewed and approved include:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover letter	1.0	15 th Nov 2016
NEAF	1.0	15 th Nov 2016
Electronic authorisation for signatures		Nov 2016
Study protocol	1.0	10 th Nov 2016
Letter of support, AHCSA		5 th Oct 2016
Letter of support, AMSANT		25 th Aug 2016
Letter of support, Heart Foundation		27 th June 2016
Letter of support, WA Dept of Health		5 th May 2016
HREC Approval, WA Dept of Health		13 th June 2016
HREC Approval, WAAHEC		13 th Oct 2016
HREC Approval, Metro North HREC		2 nd Dec 2015
Peer review, K Spilsbury		5 th Aug 2016
PHRN Application Form	1.0	7 th Nov 2016
SA NT Datalink Feasibility letter		2 nd Oct 2016
Linked Data Variables List	1.0	8 th Oct 2016

Sites covered by this approval:

- SA Department for Health and Ageing

Please note the following conditions of approval:

- The research must be conducted in accordance with the 'National Statement on Ethical Conduct in Human Research.'
- A progress report, at least annually, must be provided to the HREC.
- When the project is completed, a final report must be provided to the HREC.
- The HREC must be notified of any complaints by participants or of adverse events involving participants.
- The HREC must be notified immediately of any unforeseen events that might affect ethical acceptability of the project.
- Any proposed changes to the original proposal must be submitted to and approved by the HREC before they are implemented.
- If the project is discontinued before its completion, the HREC must be advised immediately and provided with reasons for discontinuing the project.

HREC approval is valid for 3 years from the date of this letter.

Should you have any queries about the HREC's consideration of your project please contact the Executive Officer of the HREC, on (08) 8226 7235 or Health.HumanResearchEthicsCommittee@sa.gov.au

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a SA Health site until separate authorisation from the Chief Executive or delegate of that site has been obtained via the completion of a Site Specific Assessment form. Please contact David van der Hoek via email at ResearchGovernance@health.sa.gov.au to discuss this process further.

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.

The HREC wishes you every success in your research.

Yours sincerely



for

**Andrew Alston
DEPUTY CHAIRPERSON
HUMAN RESEARCH ETHICS COMMITTEE**

13/12/2016