

5th March 2018

Dr Judith Katzenellenbogen
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The University of Western Australia
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Perth WA 6009

AH&MRC Ethics
Committee
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Dear Dr Judith Katzenellenbogen,

HREC Reference number: 1363/18

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

Thank you for submitting the above research project for single ethical review. This project was considered by the AH&MRC Ethics Committee at its meeting held on 5th February 2018.

I am pleased to advise you that the above research project meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* and ethical approval for this research project has been granted by AH&MRC Ethics Committee.

The approved documents include:

Document	Version	Date
1. RHD Linked Data AHMRC HREC cover letter 180117.docx		
2. AHMRC Ethics Committee application cover sheet 180115.doc	Version 3	
3. NSW Population and Health Services Research Ethics Committee application (HREA)180110.pdf		
4. Combined CHeRel application form including study protocol.docx	Version 5	
5. Prince Charles Hospital Human Research Ethics Committee approval letter (QLD).pdf		
6. WA Health HREC approval letter.pdf		
7. SA HREC approval letter.pdf		
8. Top End Human Research Ethics Committee approval letter (for Top End and Central NT).pdf	Version 5	
9. WAAHEC approved letter.pdf		
10. AHREC (SA) approval letter.pdf		
11. Aboriginal Medical Services Alliance Northern Territory (AMSANT) support letter.pdf		

12. Aboriginal Health Council of Australia (South Australia) support letter.pdf		
13. WA Health Aboriginal Health Policy Directorate support letter.pdf		
14. Heart Foundation of Australia Cultural Lead support letter.pdf		
15. RE: RESPONSE 2: KAHPF Research sub-committee project form – 2016-010 – RHD Linked data study		
16. Response to KAHPF research sub-committee queries.docx		

Approval of this project from AH&MRC Ethics Committee is valid from 5th March 2018 to 4th March 2019 subject to the following conditions being met:

- The Coordinating Principal Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any event that requires a modification to the protocol or other project documents and submit any required amendments in accordance with the instructions provided by the HREC. These instructions can be found at www.ahmrc.org.au/ethics .
- The Coordinating Principal Investigator will submit any necessary reports related to the safety of research participants in accordance with AH&MRC Ethics Committee policy and procedures. These instructions can be found at www.ahmrc.org.au/ethics .
- The Coordinating Principal Investigator will report to the AH&MRC Ethics Committee annually in the specified format and notify the HREC when the project is completed at all sites.
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee if the project is discontinued at a participating site before the expected completion date, with reasons provided.
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of any plan to extend the duration of the project past the approval period listed above and will submit any associated required documentation. Instructions for obtaining an extension of approval can be found at www.ahmrc.org.au/ethics .
- The Coordinating Principal Investigator will notify the AH&MRC Ethics Committee of his or her inability to continue as Coordinating Principal Investigator including the name of and contact information for a replacement.
- The Coordinating Principle Investigator will submit the final draft report from the research, and any publication or presentation where data or findings are presented, to the AH&MRC Ethics Committee to be reviewed for compliance with ethical and cultural criteria prior to:
 - Any submission for publication; and/or
 - Any dissemination of the report

This letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

Should you have any queries about the AH&MRC Ethics Committee's consideration of your project please contact Mr Sonny Green. The AH&MRC Ethics Committee Terms of Reference, Standard Operating Procedures, membership and standard forms are available from www.ahmrc.org.au or from the Ethics Coordinator.

The AH&MRC Ethics Committee wishes you every success in your research.

Yours faithfully,



Ms Val Keed
Chairperson
AH&MRC Ethics Committee