

HUMAN RESEARCH ETHICS COMMITTEE AHEC EC00422

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Associate Professor Judith Katzenellenbogen Comibed Universities Centre for Rural Health The University of WA 35 Stirling Hwy CRAWLEY WA 6009

Dear Associate Professor Katzenellenbogen

Project #2016/29 - Baseline for monitoring the burden of rheumatic heart disease in Australian jurisdictions: Western Australian component [SHORT TITLE: Burden of rheumatic heart disease in Western Australia]

Date of commencement: 1/07/2016 Date of next annual progress report: 8/06/2017

Research team: Judith Katzenellenbogan, Nick de Klerk, Jonathon

Carapetis, Frank Sanfilippo, Karen Dempsey, Marian Abouzeid, Julie Marsh, Jeff Cannon, Annette Regan

DOH data required: Yes
Data linkage required: Yes

Datasets to be accessed: Mortality Register

Emergency Department Data Collection Hospital Morbidity Data Collection

Infectious Disease Register

iPharmacy ASCribe

WA Rheumatic Heart Disease Register

Date of ethical review: 8 June 2016 Ethics approval validity: 8 June 2019

Approval for the following sites: Telethon Kids Institute, Menzies School of Health

Research/RHD Australia

I am pleased to advise that the Department of Health WA Human Research Ethics Committee (DOH HREC) has granted **ethical approval** for this project.

The Committee considered your application under the Guidelines under Section 95A of the Privacy Act 1988 and the National Statement on Ethical Conduct in Human Research 2.3.10 and was satisfied that it met the criteria to grant a waiver of consent.

This letter constitutes <u>ethics approval only</u>. You will not receive the data requested for your project until the release of the data has also been approved by the data steward.

As Principal Investigator you are responsible for the ethical conduct of the project and the security of the personal health information.

This approval is subject to your continued compliance with your obligations under the Practice Code for the Use of Personal Health Information including the following conditions. You are required to:

- 1. Report to the DOH HREC anything which might warrant review of ethical approval of the project including;
 - any breaches or complaints and any adverse events affecting the security and confidentiality of the data; and
 - unforeseen events that might affect the continued ethical acceptability of the project.
- 2. Notify the DOH HREC if the project is discontinued or withdrawn before the expected date of completion and to give reasons for this action.
- 3. Provide an annual progress report to the DOH HREC and a final report at the completion of the project.
- 4. Obtain approval from the DOH HREC for;
 - any changes or amendments to the research protocol, including methodology, data required, duration of the project and any changes to the approved data storage arrangements;
 - any changes of personnel in the research team, and provide a DOH Confidentiality Agreement/Confidentiality Acknowledgement form for any addition to the research team.

We wish you well with your project.

Yours sincerely

Judy Allen

Chair

Department of Health WA Human Research Ethics Committee

Honorary Fellow Faculty of Law University of Western Australia

13 June 2016