

21 December 2016

A/Professor Judith Katzenellenbogen  
Telethon Kids Institute  
100 Roberts Rd  
Subiaco WA 6008

**Ethics Administration Office**  
**File Reference Number:** HREC-2016-2705  
**Phone:** (08) 8946 8687 or (08) 8946 8692  
**Email:** ethics@menzies.edu.au

Dear A/Prof Katzenellenbogen,

**HREC Reference Number: 2016-2705**

**Project Title: *Baseline for monitoring the burden of rheumatic heart disease in Australian jurisdictions: Northern Territory component***

Thank you for your letter dated 19/12/2016 and taking the time to respond to the issues of concern identified by the Fast Track sub-committee of the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (HREC). This project was considered by members of the HREC and the Aboriginal Ethics Sub-Committee (AESC), and assessed against guidelines for human research including the NHMRC *National Statement on Ethical Conduct in Human Research 2007*.

I am pleased to advise that **full ethical approval** of this research project has been granted following assessment by representatives of both the AESC and the HREC. Please note that approval applies only to research conducted after the date of this letter and continued approval is dependent on annual reporting.

**Approval Date: 21/12/2016**

**Approved Timeline: 21/12/2016 – 31/12/2020**

**Annual progress report due: 31/12/2017**

The nominated participating site/s in this project is/are:

- **Menzies School of Health Research**
- **NT Dept of Health**
- **NT Centre for Disease Control**

**The following datasets subject to data custodian approval:**

- **NT Primary Health Care collection**
- **NT Rheumatic Heart Disease Register**
- **NT Deaths Register**
- **NT Emergency Department Activity Collection**
- **NT Inpatient Activity**
- **NT Paediatric cardiac surgery database**
- **National Cardiac surgery database**

**The documents listed below are approved:**

Document	Version	Date
Initial Application - NEAF	xx	7/11/2016
Part D of HREC Application Form		7/11/2016

**The documents listed below are noted:**

Document	Version	Date
Support letter - AMSANT	xx	25/08/2016
Approval letter – WA Dept of Health HREC		13/06/2016
Approval letter - WAAHEC		13/10/2016
Approval letter – Qld Metro North HREC		2/12/2015
Peer review report – SA Health		5/08/2016
SANT Datalink Technical Feasibility		2/10/2016

**APPROVAL IS SUBJECT TO** the following conditions being met:

1. The Coordinating Principal Investigator will **immediately report anything that might warrant review** of ethical approval of the project.
2. The Coordinating Principal Investigator will notify the Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research (HREC) of any event that requires a **modification or amendment 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 on the Menzies' website.
3. The Coordinating Principal Investigator will submit any necessary reports related to the **safety of research participants (e.g. protocol deviations, protocol violations)** in accordance with the HREC's policy and procedures. These guidelines can be found on the Menzies' website.
4. The Coordinating Principal Investigator will **report** to the HREC **annually** and notify the HREC when the project is completed at all sites using the specified forms. Forms and instructions may be found on the Menzies' website.
5. The Coordinating Principal Investigator will notify the HREC if the project is **discontinued at a participating site before the expected completion date**, and provide the reason/s for discontinuance.
6. The Coordinating Principal Investigator will notify the HREC of any plan to **extend the duration of the project past the approval period listed above** and will submit any associated required documentation. The preferred time and method of requesting an extension of ethical approval is during the **annual progress report**. However, an extension may be requested at any time.
7. The Coordinating Principal Investigator will notify the HREC of his or her **inability to continue as Coordinating Principal Investigator**, including the name of and contact information for a replacement.
8. The safe and ethical conduct of this project is entirely the responsibility of the investigators and their institution(s).
9. Researchers should immediately report anything which might affect continuing ethical acceptance of the project, including:
  - Adverse effects of the project on participants and the steps taken to deal with these;
  - Other unforeseen events;
  - New information that may invalidate the ethical integrity of the study; and
  - Proposed changes in the project.
10. Approval for a further twelve months, within the original proposed timeframe, will be granted upon receipt of an annual progress report if the HREC is satisfied that the conduct of the project has been consistent with the original protocol.
11. Confidentiality of research participants should be maintained at all times as required by law.
12. The Patient Information Sheet and the Consent Form shall be printed on the relevant site letterhead with full contact details.
13. The Patient Information Sheet must provide a brief outline of the research activity including: risks and benefits, withdrawal options, contact details of the researchers and must also state that the Human Research Ethics Administrators can be contacted (telephone and email) for information concerning policies, rights of participants, concerns or complaints regarding the ethical conduct of the study.
14. You must forward a copy of this letter to all Investigators and to your institution (if applicable).

**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 wish to discuss the above research project further, please contact the Ethics Administrators via email: [ethics@menzies.edu.au](mailto:ethics@menzies.edu.au) or telephone: (08) 8946 8687 or (08) 8946 8686.

Yours sincerely,



Dr Lewis Campbell  
**Chair**  
**Human Research Ethics Committee**  
**of the Northern Territory Department of Health**  
**and Menzies School of Health Research**  
<http://www.menzies.edu.au/ethics>

**This HREC is registered with the Australian National Health and Medical Research Council (NHMRC) and operates in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research (2007)*. NHMRC Reg no. EC00153**

