# ETHICS APPROVAL & GOVERNANCE AUTHORISATION

13th June 2018

Professor Andrew Steer
Paediatric Infectious Disease
The Royal Children's Hospital Melbourne
Flemington Road
Parkville Victoria 3052

Dear Prof Steer

**Project Title: Does Mass Drug Administration for Scabies Result in Control of Serious Bacterial Complications? A Proof of Concept Towards Global Elimination**

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**HREC Reference Number: HREC/18/RCHM/127**
**RCH HREC Reference Number: 38020A**

I am pleased to advise that the above project has received ethical approval from The Royal Children's Hospital Melbourne Human Research Ethics Committee (HREC).

The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

The amendment has also received governance authorisation at the Melbourne Children's Campus (incorporating The Royal Children's Hospital, Murdoch Children's Research Institute and the University of Melbourne Department of Paediatrics).

**HREC Approval Date:** 13th June 2018*
*Please note the HREC are no longer issuing pre-determined approval periods. Ethical approval is now ongoing, subject to the submission of an annual report on the anniversary of approval.*

**Participating Sites**:
Ethical approval for this project applies at the following sites:

| Site Name |
|---|
| • The Melbourne Childrens Campus to be conducted in Fiji. |

**Approved Documents:**
The following documents have been reviewed and approved:

| Document | Version | Date |
|---|---|---|
| Protocol | 2 | 8th May 2018 |
| PIS for Ivermectin and Permethrin MDA | 2 | 28th May 2018 |
| PIS CF Hospital Surveillance Adult | 2 | 28th May 2018 |
| PIS CF Hospital Surveillance Child | 2 | 28th May 2018 |
| IS & Informed Consent Interviews | 2 | |
| IS & Informed Consent Community Survey | 2 | |
| PIS CF Storage Biological Specimens Adult | 2 | 28th May 2018 |
| PIS CF Storage Biological Specimens Child | 2 | 28th May 2018 |

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| PIS CF Village Skin Examination Adult | 2 | 28th May 2018 |
| PIS CF Village Skin Examination Child | 2 | 28th May 2018 |

**Site Specific Assessment**:
Site-specific governance authorisation must be obtained by each participating site before the study can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator at each site covered by this ethics approval to assist each site PI with obtaining governance approval to commence the project at that site.

**Conditions of Ethics Approval:**

- You are required to submit to the HREC:
  - An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the HREC.
  - A comprehensive Final Report upon completion of the project.
- Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).
- The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.

Yours sincerely

**Jennifer Luplow**
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