11 March 2015

Dr S Chua 55 Hyland Tce ROSLYN PARK 4072

Dear Dr Chua



Research Secretariat

Level 2, Samuel Way Building 72 King William Road

Tel 08 8161 6390 Tel 08 8161 6521 www.wch.sa.gov.au

Re: Antimicrobial resistance patterns of paediatric Urinary Tract Infections in South Australia. HREC/15/WCHN/11. Ethics expiry date: 28/2/18

Lead HREC for the above study for the following institutions/sites:
Women's & Children's Health Network

The above Low and Negligible Risk application was considered by the WCHN Human Research Ethics Committee at its meeting on 25th February 2015. I am pleased to advise that your protocol has been granted full ethics approval and meets the requirements of the *National Statement on Ethical Conduct in Human Research*.

The Committee considered that the conditions of 2.3.10 of the *National Statement on Ethical Conduct in Human Research* had been met and hence approved the waiver of consent to access medical records. This approval is on the proviso that the accessing of medical records at WCHN will be by a WCHN staff member. It should be noted that the Committee does not in general approve non-WCHN persons having access to WCHN patients' personal information without consent.

Specifically, the following documents have been noted/approved:

| Document | Version | Date |
|-----------------|---------------|------------|
| LNR Application | AU/15/646C115 | 30/12/2014 |

This letter constitutes advice on ethical consideration only. You must not commence this research project at a site until you have obtained separate research governance approval from the site concerned. A copy of this letter should be forwarded to all site investigators for submission to the relevant Research Governance Officer.

At the WCHN, or any other SA Health site, separate authorisation from the Chief Executive or delegate of that site must be obtained through a Site Specific Assessment (SSA) request. For information on this process at the WCHN, please contact the WCHN Research Governance Officer, Ms Katherine McPhail (telephone 8161 6688, email katherine.mcphail@health.sa.gov.au).

I remind you approval is given subject to:

- immediate notification of any serious or unexpected adverse events to participants;
- immediate notification of any unforeseen events that might affect continued ethical acceptability of the project;
- submission of any proposed changes to the original protocol. Changes must be approved by the Committee before they are implemented;
- immediate advice, giving reasons, if the protocol is discontinued before its completion;
- •submission of an annual report on the progress of the study, and a final report when it is completed to the WCHN Research Governance Officer. It is your responsibility to provide these reports, without reminder. The proforma for the report may be found on the WCHN Research Governance and Ethics website.



Approval is given for three years only. If the study is more prolonged than this, an extension request should be submitted unless there are significant modifications, in which case a new submission may be required. Please note the expiry date in the title above and include it in future communications.

Yours sincerely

TAMARA ZUTLEVICS (DR)

CHAIR

WCHN HUMAN RESEARCH ETHICS COMMITTEE