Government of **Western Australia**
Department of **Health**
Child and Adolescent Health Service

Dr Barry Clements
Department of Respiratory Medicine
Princess Margaret Hospital for Children
Roberts Road
SUBIACO WA 6008

Dear Dr Clements

REGISTRATION NUMBER: **2013073EP**

TITLE: A phase III single centre randomised double blind comparator controlled parallel group pilot study of Ca-EDTA added to inhaled Tobramycin vs Tobramycin alone as adjuctive therapy to a course of standard treatment for cystic fibrosis children admitted to hospital with a pseudomonas aeruginosa pulmonary exacerbation

MEETING DATE: **19 September 2013**

RGO and Ethics requirements satisfied 19 September 2013

The Princess Margaret Hospital for Children Ethics Committee and the Research Governance Office consider that the study protocol conforms to the requirements of the NHMRC *Statement on Ethical Conduct in Human Research (National Statement)* and resolved at the meeting to recommend the protocol for approval to the Chief Executive. This recommendation has been ratified by the Child and Adolescent Health Service.

The Ethics Committee does however wish to be informed immediately of:

I. any untoward effects experienced by any participant in the trial where those effects in degree or nature were not anticipated by the researchers, and steps taken to deal with these,

II. substantial changes in the research protocol together with an indication of ethical implications, and

III. other unforseen events.

Princess Margaret Hospital for Children
Roberts Road Subiaco WA 6008
GPO Box D184 Perth WA 6840
Tel: (08) 9340 8222 Fax: (08) 9340 8111
www.cahs.health.wa.gov.au

The Ethics Committee has been charged with the responsibility of keeping the progress of all approved research under surveillance. A copy of the final result must be forwarded to the Committee upon completion of the research or if the research is not completed within twelve months you are asked to submit a progress report and annually thereafter. This information should include:

a) The status of the project (completed/in progress/abandoned/not commenced). In the event that a project does not commence within 12 months of being approved by the Ethics Committee the study must be resubmitted to the Committee for approval.

b) Compliance with conditions of ethical approval, including security of records and procedures for consent.

c) Compliance with any special conditions stated by the Ethics Committee as a condition of approval.

d) Results from the study to date, including outcome.

Please note that approval for studies is for **three years** and if the research is not completed within that period of time, a request for an extension of time should be submitted for consideration. In the event that a project does not commence within **12 months** of being approved by the Ethics Committee, the study must be resubmitted to the Committee for approval.

In accordance with the NHMRC National Statement on Ethical Conduct in Human Research Chapter 5.5.3, researchers have a significant responsibility in monitoring and must submit the following to the Ethics Committee:

- Annual Reports on the anniversary of the approval date of the study
- Adverse event reports as received
- Amendments and extensions to the study to be requested in adequate time

Please quote the above registration number on all correspondence.

Yours sincerely

PP
Dr Mark Salmon
Executive Director
Medical Services

1 October 2013

- The Ethics Committee is constituted, and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Research Involving Humans