



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

Our Ref: 2013073EP

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

Dear Dr Clements

**REGISTRATION NUMBER: 2013073EP**

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

**MEETING DATE: 26 August 2014**

Thank you for your letter received by this office enclosing the following amendments:

Addition of New Site - Sir Charles Gairdner Hospital Respiratory Department

The PMH SCIENTIFIC ADVISORY SUB-COMMITTEE reviewed your request for the abovementioned amendments at its meeting on 26/08/2014 and recommended the amendments for approval.

It should be noted that all other aspects of the approval remain unchanged. This is so, in particular, in relation to the progress reports required and regarding any further amendments to the protocols.

**Please quote the above trial number 2013073EP on all correspondence associated with this trial.**

Yours sincerely

**Dr Mark Salmon**  
**Executive Director**  
**Medical Services**

11 September 2014

- The PMH SCIENTIFIC ADVISORY SUB-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

Child and Adolescent Health Service  
Roberts Road, Subiaco WA 6008  
GPO Box D184 Perth WA 6840  
Tel: (08) 93408222 Fax: (08) 93408111  
[www.caHS.health.wa.gov.au](http://www.caHS.health.wa.gov.au)