

FINAL R&D APPROVAL

Joint Research and Development Office

Professor Jonathan Grigg
[REDACTED]
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[REDACTED]
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Tel: [REDACTED]
Fax: [REDACTED]

9th September 2010

Dear Professor Grigg,

Re: Parent-determined oral Montelukast Therapy for preschool wheeze with stratification for arachidonate-5-lipoxygenase (ALOX5) promoter genotype: WAIT Trial

ReDA Reference: 006539
CSP REF: 35170

I am now happy to inform you that the Joint R&D Office of Barts and The London NHS Trust and Queen Mary, University of London has arranged full indemnity cover for your study against any negligence that might occur during the course of your project.

Please note that all research with an NHS element is subject to the Research Governance Framework for Health and Social Care 2005. If you are unfamiliar with the standards contained in this document, or the BLT and QMUL policies that reinforce them, you can obtain details from the Joint R&D Office, tel [REDACTED] or go to <http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en>.

You must stay in touch with the Joint R&D Office during the course of the research project, particularly if/ when:

- There is a change of Principal Investigator;
- The project finishes;
- Amendments are made, whether minor or substantial.

This is necessary to ensure that your indemnity cover is valid. Should any Serious Adverse Events (SAEs) occur it is **essential** that you inform the Sponsor within 24 hours. If patients or staff are involved in an incident, you should also contact the Clinical Risk Manager on [REDACTED].

I hope the project goes well, and if you need any help or assistance during its course, please do not hesitate to contact the Office.

Yours sincerely,

[REDACTED]

Gerry Leonard
Head of Research Resources

