



## Health Research Authority

### NRES Committee South West - Central Bristol

Bristol Research Ethics Committee Centre  
Whitefriars  
Level 3, Block B  
Lewin's Mead  
Bristol BS1 2NT  
Email: nrescommittee.southwest-bristol@nhs.net

07 November 2013  
**REISSUED due to Admin Error**  
11 November 2013

Alastair Hay  
University of Bristol  
Canyng Hall, 39 Whatley Road  
Bristol  
BS8 2PS

Dear Hay

**Study title:** What is the clinical and cost effectiveness of oral steroids in the treatment of acute lower respiratory tract infection (LRTI)? A placebo controlled randomised trial  
**REC reference:** 12/SW/0180  
**Protocol number:** UoB1581  
**EudraCT number:** 2012-000851-15  
**Amendment number:** 2013/09/01 1.4  
**Amendment date:** 25 September 2013  
**IRAS project ID:** 102138

The above amendment was reviewed on 01 November 2013 by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
European Commission Notification of Substantial Amendment Form		25 September 2013
Covering Letter		04 October 2013
Participant Consent Form : Consent-to-Contact	1.0	05 September 2013
Participant Information Sheet: Booklet	1.4	05 September 2013

Advertisement	1.1	28 August 2013
Protocol	1.4	23 September 2013
Case Report Form	1.2	23 September 2013
Participant Information Sheet: Summary	1.4	05 September 2013

### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

### R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

### Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

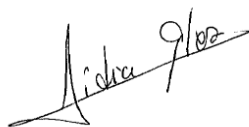
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>12/SW/0180:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Dr Pamela Cairns (Chair)**

**Chair**

E-mail: [nrescommittee.southwest-bristol@nhs.net](mailto:nrescommittee.southwest-bristol@nhs.net)

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Mrs Rachel Avery, Avon Primary Care Research Collaborative  
Dr Birgit Whitman, University of Bristol, Research & Enterprise Development*

**NRES Committee South West - Central Bristol**

**Attendance at Sub-Committee of the REC meeting on 01 November 2013**

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mr Trevor Beswick (AV-C)	Director - SW Medicines, Information & Training	Expert
Dr Pamela Cairns (Chair)	Consultant Neonatologist	Expert
Miss Lidia Gonzalez	REC Admin Assistant	None