Health Research Authority
NRES Committee South West - Central Bristol
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25 October 2012

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

Dear Dr 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**

Thank you for your letter of 02 October 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites listed in the application, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents
The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		31 May 2012
Evidence of insurance or indemnity	Letter from UoB	10 May 2012
Investigator CV		19 March 2012
Letter of invitation to participant	1 (lt to GP)	31 May 2012
Other: Research Related A E Reporting Policy	3.5	20 February 2012
Participant Consent Form	1.2	28 September 2012
Participant Information Sheet	1.2(Booklet)	28 September 2012
Participant Information Sheet	1.2(Summary leaflet)	28 September 2012

Protocol	1.1	01 October 2012
REC application	3.4	31 May 2012
Response to Request for Further Information	Letter	02 October 2012
Sample Diary/Patient Card	1 (given by REC)	31 May 2012

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.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

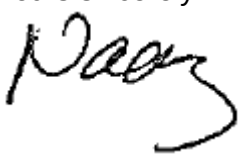
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/SW/0180	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely



pp. Dr Pamela Cairns
Chair

Email: naaz.nathoo@UHBristol.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers" *[SL-AR1]*

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

NRES Committee South West - Central Bristol

Attendance at Sub-Committee of the REC meeting on 22 October 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Patsy Hudson	Coach/Mentor	Yes	
Mr Geoffrey Jones	Retired Solicitor	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Naazneen Nathoo	Coordinator