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NHS

National Research Ethics Service

Nottingham Research Ethics Committee 2
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08 April 2009

Prof Philip Bath
Stroke Assocaitation Professor of Stroke Medicine
Univerisity of Nottingham
Division of Stroke Medicine
Clinical Sciences Building, City Hospital
Nottingham, NG5 1PB

Dear Prof Bath,

Full title of study:	**Determining the potential of ambulance-based randomised controlled trials in patients with hyperacute stroke; assessment of GTN in lowering blood pressure**
REC reference number:	**09/H0408/5**
Protocol number:	**1.1**
EudraCT number:	**2007-004766-40**

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

The further information has been considered on behalf of the Committee by the Chair.

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

The favourable opinion applies to the research sites listed on the attached form.

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 at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

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.

Approved documents

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

Document	*Version*	*Date*
Application	AB/134957/1 & C/134957/219893/1	06 January 2009
Protocol	1.1	01 July 2008
Investigator CV		06 October 2008
Letter of Response to Unfavourable Opinion letter		17 December 2008
Unfavourable Opinion letter from Nottingham 2 REC		05 March 2008
Participant Consent Form: after assent form	1	01 November 2007
Participant Information Sheet: Relatives - to continue in trial once initial consent has been taken by paramedic	1.1	05 September 2006
Evidence of Insurance		05 August 2008
GP/Consultant Information Sheets	1.0	01 November 2007
Letter from Sponsor		18 December 2008
Request form for authorisation from the MHRA (Annex 1 to ENTR/CT1) without enclosures		
Letter from Prof P Sandercock		01 December 2008
Response to Request for Further Information		
Participant Consent Form: Patients	1.1	01 February 2009
Participant Consent Form: Ambulance limited consent sheet: Proxy consent from paramedic	1.0	01 March 2009
Participant Consent Form: Ambulance limited consent sheet: Proxy consent from relative	1.0	01 February 2009
Participant Consent Form: Ambulance limited consent sheet	1.0	01 February 2009
Participant Information Sheet: Patients	1.3	01 February 2009
Participant Information Sheet: Ambulance	1.0	01 March 2009

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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

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.

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
- 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.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0408/5	**Please quote this number on all correspondence**

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

Yours sincerely

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Dr M Hewitt/Ms L Ellis
Chair/Co-ordinator

Email: linda.ellis@nottspct.nhs.uk

Enclosures: "After ethical review – guidance for researchers"
Site approval form

Copy to: Mr Paul Cartledge, Nottingham University

R&D Department for NHS care organisation at lead site - NUH (via email)