Nottingham University Hospitals NHS Trust

Please reply to: Research and Development
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Professor PMW Bath
Division of Stroke Medicine
Clincal Sciences Building
Nottingham City Hospital
Nottingham University Hospitals NHS Trust
NG7 1PB

30 September 2009

Dear Professor Bath

ID: 08SR003 **Determining the potential of ambulance-based randomised controlled trials in patients with hyperacute stroke; assessment of GTN in lowering blood pressure**

The R&D Department has considered the following documents:

- NHS REC Application form, version 5.6
- Protocol, version 1.1 dated 28/07/08
- Participant Information Sheet, version 1.3 dated 01/02/09
- Participant information sheet: Relative version 1.1 dated 05/09/06
- Participant information sheet: Ambulance version 1.0 dated 01/03/09
- Participant consent form: Ambulance limited consent sheet (Proxy consent from relative) version 1.0 dated 01/02/09
- Participant consent form: Ambulance limited consent sheet (Proxy consent form paramedic) version 1.0 dated 01/03/09
- Participant consent form version 1.1 dated 01/02/09
- GP information letter version 1.0 dated 01/11/07

Your study now has R&D approval, on the understanding and provision that you will follow the conditions set out below.

Conditions of Approval

That you:

1. Accept the responsibility of Chief/Principal Investigator as defined in the current Research Governance Framework.
2. Request written approval from the R&D department for any change to the approved protocol/study documents you wish to implement
3. Ensure all study personnel, not employed by the Queens Medical Centre, University Hospital NHS Trust Nottingham or the City Hospital NHS Trust Nottingham, hold either honorary Contracts/letters of access with this Trust, before they have access to any facilities, patients, staff, their data, tissue or organs.
4. Report any Serious Adverse Event involving the Trust to the R&D department, using the Trust 'policy for research safety reporting in human subjects'. Policy available from the R&D Department.
5. Complete the R&D Research Governance interim and final reports as requested.
6. Comply with the regulatory requirements and legislation relating to: Data Protection, Trust Caldicott Guidelines, Health and Safety and the use of Human Tissue for research purposes.
7. Comply with the current Research Governance Framework, available at

www.doh.gov.uk or via the R&D office or Research Governance Web-site.

8. Agree to conduct this research project in accordance with ICH Good Clinical Practice and/or the MRC Guidelines for Good Clinical Practice (as appropriate)
9. Must not start your project until you have received written approval from the relevant ethics committee.

This approval letter constitutes a favourable Site Specific Assessment (SSA) for this site.

Please note that the R&D department has a database containing study related information, and personal information about individual investigators e.g. name, address, contact details etc. This information will be managed according to the principles established in the Data Protection Act.

Yours sincerely

Dr Brian Thomson

Director of R&D

cc Nottingham Research Ethics Committee