Nottingham University Hospitals NHS Trust

Please reply to: Research and Development
E11 Curie Court
Queen's Medical Centre Campus
Derby Road
Nottingham
NG7 2UH

Telephone: 0115 970 9049
Fax: 0115 849 3295
E-mail:

14 April 2010

Professor PMW Bath
Division of Stroke Medicine
Clincal Sciences Building
Nottingham City Hospital
Nottingham University Hospitals NHS Trust
NG7 1PB

Dear Professor Bath

ID: 09SR007 **Prevention Of Decline in Cognition After Stroke Trial(PODCAST): A factorial randomised controlled trial of intensity versus guideline lowering of blood pressure and lipids.**

The R&D Department has considered the following documents:

REC Application form, 18461/51865/1/950, dated 24 July 2009
Protocol, version 1.1, dated 12 October 2009
Participant Information Sheet: Main Study, version 1.1, dated 12 October 2009
Participant Information Sheet: If Patient Loses Capacity to Maintain Consent, version 1.1, dated 12 October 2009
Participant Consent Form: Main Study - Screening, version 1.1, dated 12 October 2009
Participant Consent Form: Main Study, version 1.1, dated 12 October 2009
Participant Consent Form: Main Study Informant - if Participant Loses Capacity to Maintain Consent, version 1.1, dated 12 October 2009
GP/Consultant Information Sheets - Podcast Study Enrolment, version 1.1, dated 12 October 2009
Evidence of Insurance or Indemnity, dated 28 July 2009
GP Letter - Re: Patient Developing Probable Dementia, version 1.0, dated 12 October 2009
Participant Information Sheet: Main Study - Informant, version 1.0, dated 12 October 2009
Participant Information Sheet: Sub-Studies - Informant (if Participant Loses Capacity to Maintain Consent), version 1.0, dated 12 October 2009
Participant Information Sheet: Sub-Studies, version 1.1, dated 12 October 2009
Participant Consent Form: Sub-Studies, version 1.0, dated 12 October 2009
Participant Consent Form: Informant: as Informant for the Study, version 1.0, dated 12 October 2009
Participant Consent Form: Sub-Studies - Informant - is Participant Loses Capacity to Maintain Consent, version 1.0, dated 12 October 2009
Information for GP: Regarding Patient Screening for Podcast Study, version 1.0, dated 12 October 2009

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

Please remember to keep Good Clinical Practice training for the study team up to date.

Conditions of Approval

That you:

1. Comply with all relevant laws, regulations and codes of practice applicable to the trial including but not limited to, the UK Clinical Trials Regulations, Medicines for Human Use (Clinical Trial) Regulations 2004, principles of Good Clinical Practice, the World Medical Association Declaration of Helsinki entitled 'Ethical Principles for Medical Research Involving Human Subjects' (1996 version), the Human

Rights Act 1998, the Data Protection Act 1998 the Medicines Act 1968, the NHS Research Governance Framework for Health and Social Care (version 2 April 2005). Should any of these be revised and reissued the latest version of the relevant laws and regulations will apply. Copies of the regulations are available from the R&D Office or via the R&D website http://nuhrise.org

2. For NUH sponsored studies accept the responsibilities as outlined in the "Clinical Trial Delegation of Sponsorship responsibilities to Chief Investigator" agreement.

3. Request written approval from the R&D department, Ethics Committee and MHRA (as appropriate) for any Protocol Amendments, changes to study documentation or changes to study team.

4. Ensure all study personnel, not employed by the Nottingham University Hospitals NHS Trust hold either honorary contracts/letters of access with this Trust, before they have access to any patients or staff, their data, tissue or organs or any NUH facilities.

5. According to R&D SOP 11 - "Adverse Event Monitoring, Recording and Reporting for investigators" report any Serious Adverse Events to the R&D department.

6. According to R&D SOP 12 - "Protocol Violations and Serious Breach Reporting" report any Serious Breach of the UK Clinical Trial regulations in connection with the trial or Serious Breach of the protocol, immediately after becoming aware of the breach to R&D.

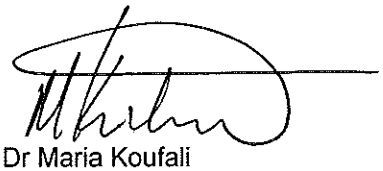
7. complete Annual Safety, Progress reports and End of Study reports as required by R&D, Ethics Committee and the MHRA.

8. Notify R&D within 7 calendar days of the first patient or healthy volunteer recruited onto the study, as well as the detail of the specific recruitment date. Please email the recruitment notification to rdmon@nuh.nhs.uk.

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 / Dr Maria Koufali

Director of R&D / Assistant Director Research and Innovation

cc Nottingham Research Ethics Committee