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23 July 2010

Mr Robert Johnson
Vice Chairman
Nottingham Research Ethics Committee 1
1 Standard Court
Park Row
Nottingham NG1 6GN

Dear Mr Johnson,

Study Title: **Prevention of Decline in Cognition After Stroke Trial (PODCAST): a factorial randomised trial of intensive versus guideline lowering of blood pressure and lipids.**
REC reference: **09/H0403/71**

This clinical trial received a favourable opinion letter on 12th November 2009 and we plan to start recruitment in September 2010.

I am writing regarding a substantial amendment to the PODCAST trial protocol. The updated version 1.2 of the protocol primarily consists of the following changes in the running of the trial:

1. The updated protocol clarifies that the treatment algorithms are only a guide and specific drugs for individual patients should be guided by local policy and practice. To this effect, the algorithms for guideline BP and lipid management have been withdrawn and the relevant section revised and updated.
2. Informed consent: Following feedback from the Scottish REC and recruiting sites, it was felt that as all participants have consented to participate in the study, re-consenting by an informant, should participants lose capacity, was not necessary. However, as per the Mental Capacity Act 2005, England, if participants lost capacity during the trial, and the informant felt it was not in the participant's best interests to continue participation, they may choose to withdraw them from the study. The informant sheets/consent forms related to participants losing capacity have been withdrawn and the relevant sections of the protocol revised.
3. GP involvement: The protocol clarifies and updates trial related procedures involving GPs such as recruitment, GP investigations and follow-up. GPs will be provided with more information regarding the study at the time of screening and

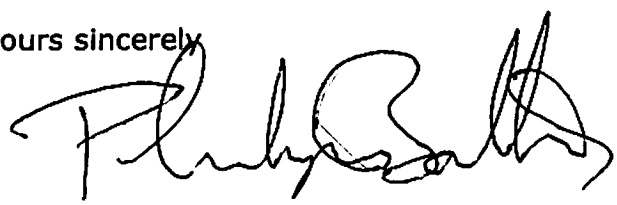
relevant Quality and Outcome Framework (QOF) indicators collected during the trial will be fed back to the GPs. A practice briefing sheet, which details GP involvement in the trial, will now be sent to them after participant screening.

4. Scan transfer and storage: This section has been updated to be compliant with the Data Protection Act and the NHS guidelines regarding transfer of electronic data.

We have altered the information sheets and consent forms to reflect the above changes. The updated documents with tracked changes are enclosed.

We request that you kindly review and approve these changes to the conduct of the trial.

Yours sincerely



Professor Philip Bath

Enclosures:

1. Podcast Protocol: Summary of changes for Version 1.2.
2. Protocol Version 1.2 dated 22 July 2010 (with tracked changes and updated document)
3. Participant Information Sheet: Main Study; Version 1.2 dated 22 July 2010
4. Participant Information Sheet: Sub Studies; Version 1.2 dated 22 July 2010
5. Participant Consent Form: Screening; Version 1.2 dated 22 July 2010
6. Participant Consent Form: Main Study; Version 1.2 dated 22 July 2010
7. Participant Consent Form: Sub Studies; Version 1.1 dated 22 July 2010
8. Informant Information Sheet; Version 1.1 dated 22 July 2010
9. Informant Consent Form; Version 1.1 dated 22 July 2010
10. GP Letter: Study Screening; Version 1.1 dated 22 July 2010
11. GP Letter: Study Recruitment; Version 1.2 dated 22 July 2010
12. GP Letter: Diagnosis of Probable Dementia; Version 1.1 dated 22 July 2010
13. GP Letter: Practice Briefing Sheet; Version 1.0 dated 22 July 2010