

Professor Philip Bath
The Stroke Association Professor of Stroke Medicine
Division of Stroke Medicine
Clinical Sciences Building
City Hospital
Nottingham
NG5 1PB
Telephone: 0115 8231765
Fax: 0115 8231767
E-mail: philip.bath@nottingham.ac.uk

29^h March 2009

Dr Martin Hewitt
Chairman
Nottingham Research Ethics Committee 2
1 Standard Court
Park Row
Nottingham
NG1 6GN

Dear Sir,

Re: Rapid Intervention with GTN in Hypertensive Stroke Trial (RIGHT)
REC reference number: 09/H0408/5

Thank you for reviewing the application for the RIGHT trial.

We have addressed the issues raised by the Nottingham Research Ethics Committee 2 on your letter dated 09 February 2009 as follows.

1. Copy of the paramedics pre-prepared script for consent in the ambulance is enclosed
2. We are unclear about what the Ethics Committee meant by 'written record of the debriefing service'. Please find enclosed the written records of the limited consent sheets. We will be happy to provide any further information you may need.
3. The ENOS (Efficacy of Nitric Oxide in Stroke Trial) data monitoring committee (DMC) minutes are confidential to Committee itself because assessments are unblinded. The 'DMC December 2008 meeting', letter from the Chair is enclosed.
4. The changes/ amendments to the patient information sheets as suggested by the ethics committee have been incorporated.
5. Date and version number are now added to the consent forms.

6. We would like to clarify the paramedic assent issue. If the patient is unable to give consent and there is no relative available then the ambulance service (paramedic) may recruit suitable patients into the first stage of the trial in the ambulance. Proxy consent from relatives will be taken when they are available for participation to continue. Once in the hospital a full patient/relative information sheet will be provided and a full informed written consent will be obtained from the patient/relative

Enclosures:

1. Limited ambulance patient consent form (version 1.0 February 2009)
2. Limited ambulance relative proxy consent form (version 1.0 February 2009)
3. Limited ambulance paramedic proxy consent form (version 1.0 March 2009)
4. Ambulance information sheet (version 1.0 March 2009)
5. 'Data Monitoring Committee Meeting Chairperson letter', for December 2008
6. Patient Information sheet (version 1.3 February 2009) with amendments as suggested
7. Consent form with date and version number of the new information sheet (Version 1.1 February 2009).

Please do not hesitate to contact me should you need any further information.

Yours sincerely,

Philip Bath BSc MB BS MD FRCPath FRCP
Stroke Association Professor of Stroke Medicine