



Health Research Authority

National Research Ethics Service

NRES Committee Yorkshire & The Humber - Sheffield

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20 November 2013

Ms Jodie Keyworth
Research Coordinator
Academic Directorate of Neurosciences
Sheffield Teaching Hospitals NHS Foundation Trust
N125d, N Floor
Royal Hallamshire Hospital
Glossop Road
Sheffield
S10 2JF

Dear Ms Keyworth

Study title:	Assessment of age and disease related cognitive impairment in normal volunteers and people with degenerative and vascular brain disease and assessment of the potential neuroplastic effect of non pharmacological treatment
REC reference:	12/YH/0474
Amendment number:	Amendment 01
Amendment date:	03 October 2013
IRAS project ID:	84442

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

Approval was sought to add two additional patient groups. These would be patients with Multiple Sclerosis and Parkinson Disease. There would also be an additional three key collaborators.

The Committee specified that in paragraph four on page one of the Participant Information Sheets the sentence starting '*Your participant will be vital...*' should be revised as this wording is too persuasive.

The Committee also thought that the information given on page two about timings and visits could be clarified as it was not exactly clear how this would vary from four weeks to twelve weeks. Please could you revise the wording.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMPs)	Amendment 01	03 October 2013
Protocol	2.0	05 November 2013
Parkinson Disease Patient Information Sheet 2	1.0	05 November 2013
Parkinson Disease Consent Form 2	1.0	05 November 2013
Multiple Sclerosis Patient Information Sheet 2	1.0	05 November 2013
Multiple Sclerosis Consent Form 2	1.0	05 November 2013

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

12/YH/0474:	Please quote this number on all correspondence
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Yours sincerely



**On behalf of
Mr Neil Sykes
Vice Chair**

E-mail: nrescommittee.yorkandhumber-sheffield@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to:

Professor Annalena Venneri
University of Sheffield

Dr Ramila Patel
Sheffield Teaching Hospitals NHS Foundation Trust

NRES Committee Yorkshire & The Humber - Sheffield

Attendance at Sub-Committee of the REC meeting on 20 November 2013

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Mrs Yvonne Stephenson	Lead Technician in the Department of Infection and Immunity	Expert
Mr Neil Sykes	Retired Engineer/ Scientist	Lay Plus