

WoSRES

West of Scotland Research Ethics Service



Dr Donald Grosset
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West of Scotland REC 1

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Date 06 May 2014
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Dear Dr Grosset

Study title: **PRoBaND: Parkinson's Repository of Biosamples and Network Datasets: Prospective observational study of Parkinson's disease with repeat clinical assessment and biobanking of blood samples.**

REC reference: **11/AL/0163**

Protocol number: **52504/1**

Amendment number: **Version 1.3, 12/02/2014 (REC Ref AM03-1)**

Amendment date: **25 April 2014**

IRAS project ID: **70980**

Thank you for submitting the above amendment, which was received on 25 April 2014. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 29 October 2013 refers).

The modified amendment was reviewed at the meeting of the Sub-Committee held on 06 May 2014. A list of the members who took part in the review is attached.

Ethical Issues to be conveyed to the Researcher

The committee were happy to approve the amendment. They had a couple of comments about wording to the L-dopa test dose- guide notes for patients. Please note that these are comments and not a requirement for approval.

The committee commented that "tick if appropriate and score though where not applicable" could be in brackets as this is instructions for the person completing the form to hand to the patient and not an instruction for the patient.

The committee also thought it might be useful for patients to call if they are unsure what to do especially with regard to feeling unable to attend having omitted a dose. This could then be added to the guide notes for patients. It does state what to do in this situation but sometimes patients prefer discussing this with a person especially with different dose times.

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved are:

Document	Version	Date
Modified Amendment	Version 1.3, 12/02/2014 (REC Ref AM03-1)	25 April 2014
Relatives Contact Sheet	1.0	12 February 2014
Site Record of Patient Contact Regarding Relatives	1.0	14 February 2014
Guide Notes for Involving Relatives in the Study	1.0	12 February 2014
L-dopa Test Dose - Guide Notes for Patients	1.0	12 February 2014
Covering Letter	E-mail	25 April 2014
Protocol	1.3	12 February 2014

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/>

11/AL/0163:

Please quote this number on all correspondence

Yours sincerely



On behalf of
Dr Peter Hutchison
Vice-Chair

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

Copy to: Dr Steven Burke, NHS Greater Glasgow and Clyde NHS R&D

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Attendance at Sub-Committee of the REC meeting on 06 May 2014

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Rosemarie Davidson	Consultant in Clinical Genetics	Expert
Dr Jane Gow	Researcher (retired)	Lay
Dr Peter Hutchison	GP (Vice Chair)	Expert

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Kirsty Sime	Senior Co-ordinator