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West of Scotland Research Ethics Service

04 JAN 2012

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West of Scotland REC 1

Ground Floor, Tennent Building Western Infirmary 38 Church Street Glasgow

G11 6NT

Date

23rd December 2011

Direct line Fax

0141-211-6238 0141-211-1847

Ref

AHT/SAJ

Dr Donald Grosset Consultant Neurologist Southern General Hospital 1345 Govan Road Glasgow G51 4TF

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:

Protocol number:

11/AL/0163 52504/1

Amendment number: Amendment date:

PRoBaND Protocol version 1.2 dated 28/10/11

19 December 2011

Thank you for submitting the above amendment, which was received on 20 December 2011. It is noted that this is a modification of an amendment previously rejected by the Committee (our letter of 6th December 2011 refers).

The modified amendment was reviewed by the Sub-Committee in correspondence. A list of the members who took part in the review is attached.

Ethical opinion

The Sub Committee require a brief explanation of the "Wearing Off" questionnaire be added to the PISs for patients diagnosed under 50 years and diagnosed in the past 3 years

The above minor amendment to come back to the Coordinator for checking and filing

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		
Reply sheet ; Tracking Parkinson's	Version	Date
Letter to patients in a local clinical service	version 1.0	18 December 2011
Expression of interest in the T		18 December 2011
Expression of interest in the Tracking of Parkinson's Study Donor Information Booklet		28 October 2011
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	To	
	College	
	London	
	version	
Summary of Proband changes	1/2011	
Advertisement		20 December 201
Questionnaire: BFI - Big Five Inventory	version 1.0	18 December 201
Questionnaire: Wearing Off Questionnaire		
GP/Consultant Information Sheets		
	version 1.1	16 December 201
Participant Consent Form	Relatives of	
	patients with	
	Parkinson's	
	disease	
	(tracked	
Participant Consent Form	changes)	
	Patients	28 October 2011
	diagnosed	2011
	with	
	Parkinson's	
	disease at	
	under 50	
	years of age	
	(tracked	* '
Participant Consent Form: Patients diagnosed with Parkinson's	changes)	1
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iocase in the past 3 years (tracked changes)	Relatives of patients with Parkinson's	
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articipant Information Sheet	Relatives of patients with Parkinson's disease	28 October 2011
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Participant Information Sheet	Relatives of patients with Parkinson's disease (tracked changes) Patients diagnosed with Parkinson's	28 October 2011
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articipant Information Sheet	Relatives of patients with Parkinson's disease (tracked changes) Patients diagnosed with Parkinson's disease at under 50	28 October 2011
articipant Information Sheet	Relatives of patients with Parkinson's disease (tracked changes) Patients diagnosed with Parkinson's disease at under 50 years of age	28 October 2011
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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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

11/AL/0163:

Please quote this number on all correspondence

Yours sincerely

Dr John Hunter

Chair

E-mail: andrea.torrie @ggc.scot.nhs.uk

Andre & Jone

Enclosures:

List of names and professions of members who took part in the

Copy to:

৺Dr Steven Burke, Research and Development Department

West of Scotland REC 1

Attendance at Sub-Committee of the REC meeting on 02 January 2012

Name		
Dr John Hunter	Profession	Capacity
Dr Peter Hutchison	Chairman West of Scotland (1) Ethics	Expert
Mr R Sim	Vice Chair/GP	Expert
	Investments (Retired)	Lay

Also in attendance:

Name	
Miss Sharon Jenner	Position (or reason for attending)
Mrs A Torrie	Secretariat
WIGHT TONIE	Senior/Lead Administrator