WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

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07 April 2011

Dr Donald Grosset
Consultant Neurologist
NHS Greater Glasgow and Clyde Health Board
Southern General Hospital
1345 Govan Road
Glasgow G51 4TF

09 APR 2011

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**

The Research Ethics Committee reviewed the above application at the meeting held on 05 April 2011. Thank you for attending to discuss the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Other conditions specified by the REC

The PIS's should be amended as under:

Patient's diagnosed under 50 years of age:

a) page 5 - "research teaching treatments and for diagnosis" the committee wondered what this means - this should be amended as appropriate.
b) Page 6 - delete "and you can choose to withdraw your participation at any time.

Consent form - under 50 years of age.

Delete "I would like to be informed if possible about the development of new tests or treatments based on this research etc etc"

Patient's diagnosed in the past 3 years : - **Repository of Biosamples**

Page 4 - delete "In some cases research tests might indicate etc"

The researchers should ensure that all Information Sheets are in keeping with each other.

Consent Form: Repository of Biosamples

Delete "I would like to be informed if possible about the development of new tests or treatments based on this research etc etc"

Relatives of patients with Parkinson's Disease

a) Page 1 - 3rd paragraph - delete any reference to how many occasions.
b) Page 3 - "Does this mean I am going to develop PD?" - should read "develop Parkinson's Disease.
c) Page 5 - "What will happen to the clinical information" - lst line should read "The clinical information which concerns any illness you may have and your personal etc"

Consent Form:

Delete "I would like to be informed if possible about the development of new tests or treatments based on this research etc etc"

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		16 March 2011
Protocol	52504/1	16 March 2011
Participant Information Sheet: Patients Diagnosed with Parkinson's disease in the past 3 years	1.0	16 March 2011
Investigator CV	1.0	16 March 2011
REC application	3.1	17 March 2011
Participant Information Sheet: Patients Diagnosed with Parkinson's disease at under 50 years	1.0	16 March 2011
Participant Information Sheet: Relatives of patients with Parkinson's disease	1.0	11 March 2011
Participant Consent Form: Patients diagnosed with Parkinson's in the past 3 years	1.0	16 March 2011
Participant Consent Form: Patient's diagnosed with Parkinson's disease at under 50 years	1.0	16 March 2011
Participant Consent Form: Relatives of patients with Parkinson's disease	1.0	11 March 2011
GP/Consultant Information Sheets	1.0	16 March 2011

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

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.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

11/AL/0163	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr John Hunter
Chair

Email: andrea.torrie@ggc.scot.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"[SL-AR2

Copy to: *Steven Burke, R & D NHS Greater Glasgow & Clyde]*

West of Scotland REC 1

Attendance at Committee meeting on 05 April 2011

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Ian Boyd	Countryside Warden	No	
Dr Rosemarie Davidson	Consultant in Clinical Genetics	Yes	
Mr Paul Davies	Principal Pharmacist	Yes	
Mr John Devitt	Printing - retired	Yes	
Dr K Duffy	Research	No	
Mr McKenzie Gibson	Manager - Optical Company/retired Physics Lecturer	Yes	
Dr Ros Glasspool	Oncologist	No	
Dr J Godden	Scientific Officer	No	
Dr John Hunter	Chairman West of Scotland (1) Ethics	Yes	
Dr Peter Hutchison	GP/Vice Chair	Yes	
Dr J D McClure	Statistician	No	
Mr Jim McHugh	Insurance	No	
Dr T Moores	Consultant Paediatric Anaesthetist	Yes	
Dr Audrey Morrison	Research Practitioner	Yes	
Mr R Sim	Investments (retired)	Yes	
Dr M Sproule	Consultant Radiologist	No	
Prof Avril Taylor	Director, Institute for Applied Social and Health Research	No	
Mr Bill Ure	retired – Rail Consortium	Yes	

Also in attendance:

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

RESEARCH IN HUMAN SUBJECTS OTHER THAN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

After ethical review – guidance for sponsors and investigators

This document sets out important guidance for sponsors and investigators on the conduct and management of research with a favourable opinion from a NHS Research Ethics Committee. Please read the guidance carefully. A failure to follow the guidance could lead to the committee reviewing its opinion on the research.

1. Further communications with the Research Ethics Committee

1.1 Further communications during the research with the Research Ethics Committee that gave the favourable ethical opinion (hereafter referred to in this document as "the Committee") are the personal responsibility of the Chief Investigator.

2. Commencement of the research

2.1 It is assumed that the research will commence within 12 months of the date of the favourable ethical opinion.

2.2 The research must not commence at any site until the local Principal Investigator (PI) or research collaborator has obtained management permission or approval from the organisation with responsibility for the research participants at the site.

2.3 Should the research not commence within 12 months, the Chief Investigator should give a written explanation for the delay

2.4 Should the research not commence within 24 months, the Committee may review its opinion.

3. Duration of ethical approval

3.1 The favourable opinion for the research generally applies for the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, the Committee should be notified.

3.2 Where the research involves the use of "relevant material" for the purposes of the Human Tissue Act 2004, authority to hold the material under the terms of the ethical approval applies until the end of the period declared in the application and approved by the Committee.

4. Progress reports

4.1 Research Ethics Committees are expected to keep a favourable opinion under review in the light of progress reports and any developments in the study. The Chief Investigator should submit a progress report to the Committee 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted thereafter.

4.2 Progress reports should be in the format prescribed by NRES and published on the website (see www.nres.npsa.nhs.uk/applicants/after-ethical-review/).

4.3 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss the progress of the research.

5. Amendments

5.1 If it is proposed to make a substantial amendment to the research, the Chief Investigator should submit a notice of amendment to the Committee.

5.2 A substantial amendment is any amendment to the terms of the application for ethical review, or to the protocol or other supporting documentation approved by the Committee, that is likely to affect to a significant degree:

(a) the safety or physical or mental integrity of the trial participants
(b) the scientific value of the trial
(c) the conduct or management of the trial.

5.3 Notices of amendment should be in the format prescribed by NRES and published on the website, and should be personally signed by the Chief Investigator. The agreement of the sponsor should be sought before submitting the notice of amendment.

5.4 A substantial amendment should not be implemented until a favourable ethical opinion has been given by the Committee, unless the changes to the research are urgent safety measures (see section 7). The Committee is required to give an opinion within 35 days of the date of receiving a valid notice of amendment.

5.5 Amendments that are not substantial amendments ("minor amendments") may be made at any time and do not need to be notified to the Committee.

6. Changes to sites

Management permission (all studies)

6.1 For all studies, management permission should be obtained from the host organisation where it is proposed to:

- include a new site in the research, not included in the list of proposed research sites in the original REC application
- appoint a new PI or Local Collaborator at a research site
- make any other significant change to the conduct or management of a research site.

In the case of any new NHS site, the Site-Specific Information (SSI) Form should be submitted to the R&D office for review as part of the R&D application.

Site-specific assessment (where required)

6.2 The following guidance applies only to studies requiring site-specific assessment (SSA) as part of ethical review.

6.3 In the case of *NHS/HSC sites*, SSA responsibilities are undertaken on behalf of the REC by the relevant R&D office as part of the research governance review. The Committee's favourable opinion for the study will apply to any new sites and other changes at sites provided that management permission is obtained. There is no need to notify the Committee (or any other REC) about new sites or other changes, or to provide a copy of the SSI Form.

6.4 Changes at *non-NHS sites* require review by the local REC responsible for site-specific assessment (SSA REC). Please submit the SSI Form (or revised SSI Form as appropriate) to the SSA REC together with relevant supporting documentation. The SSA REC will advise the main REC whether it has any objection to the new site/PI or other change. The main REC will notify the Chief Investigator and sponsor of its opinion within a maximum of 35 days from the date on which a valid SSA application has been received by the SSA REC.

Studies not requiring SSA

6.5 For studies designated by the Committee as not requiring SSA, there is no requirement to notify the Committee of the inclusion of new sites or other changes at sites, either for NHS or non-NHS sites. However, management permission should still be obtained from the responsible host organisation (see 6.1 above).

7. Urgent safety measures

7.1 The sponsor or the Chief Investigator, or the local Principal Investigator at a trial site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

7.2 The Committee must be notified within three days that such measures have been taken, the reasons why and the plan for further action.

8. Serious Adverse Events

8.1 A Serious Adverse Event (SAE) is an untoward occurrence that:

(a) results in death
(b) is life-threatening
(c) requires hospitalisation or prolongation of existing hospitalisation
(d) results in persistent or significant disability or incapacity
(e) consists of a congenital anomaly or birth defect
(f) is otherwise considered medically significant by the investigator.

8.2 A SAE occurring to a research participant should be reported to the Committee where in the opinion of the Chief Investigator the event was related to administration of any of the research procedures, and was an unexpected occurrence.

8.3 Reports of SAEs should be provided to the Committee within 15 days of the Chief Investigator becoming aware of the event, in the format prescribed by NRES and published on the website.

8.4 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss any concerns about the health or safety of research subjects.

8.5 Reports should not be sent to other RECs in the case of multi-site studies.

9. Conclusion or early termination of the research

9.1 The Chief Investigator should notify the Committee in writing that the research has ended within 90 days of its conclusion. The conclusion of the research is defined as the final date or event specified in the protocol, not the completion of data analysis or publication of the results.

9.2 If the research is terminated early, the Chief Investigator should notify the Committee within 15 days of the date of termination. An explanation of the reasons for early termination should be given.

9.3 Reports of conclusion or early termination should be submitted in the form prescribed by NRES and published on the website.

10. Final report

10.1 A summary of the final report on the research should be provided to the Committee within 12 months of the conclusion of the study. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

11. Review of ethical opinion

11.1 The Committee may review its opinion at any time in the light of any relevant information it receives.

11.2 The Chief Investigator may at any time request that the Committee reviews its opinion, or seek advice from the Committee on any ethical issue relating to the research.