Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
PRoBaND: Parkinson's Repository of Biosamples and Network Datasets

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
(•) Other clinical trial or clinical investigation
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(•) No
b) Will you be taking new human tissue samples (or other human biological samples)?	(•) Yes	( ) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(•) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

[x] England
[x] Scotland
[x] Wales
[ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

( ) England
(•) Scotland

- ○ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which review bodies are you applying to?

- ☑ NHS/HSC Research and Development offices
- ☐ Social Care Research Ethics Committee
- ☑ Research Ethics Committee
- ☐ National Information Governance Board for Health and Social Care (NIGB)
- ☐ Ministry of Justice (MoJ)
- ☐ National Offender Management Service (NOMS) (Prisons & Probation)

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study, or any part of the study, being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the clinical care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs). For CTIMPs, please use the European Commission notice of substantial amendment form at http://eudract.emea.europa.eu/document.html.
The form should be completed by the Chief Investigator using language comprehensible to a lay person. Support in principle should be sought from the study sponsor before the amendment is submitted.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Donald	Grosset
Work Address	Southern General Hospital		
	1345 Govan Road		
	Glasgow		
PostCode	G51 4TF		
Email	donald.grosset@glasgow.ac.uk		
Telephone	01412327846		
Fax	01412327626		

Full title of study:	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.
Lead sponsor:	NHS Greater Glasgow & Clyde
Name of REC:	West of Scotland REC 1
REC reference number:	11/AL/0163
Name of lead R&D office:	Research and Development Department
Date study commenced:	
Protocol reference (if applicable), current version and date:	PRoBaND Protocol Version 1.1 dated 17/04/11
Amendment number and date:	PRoBaND Protocol Version 1.2 dated 28/10/11

Type of amendment

(a) Amendment to information previously given in IRAS

○ Yes ◉ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

Tracked version of revised Protocol, Version 1.2 dated 28/10/11, is attached.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

◉ Yes ○ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Changes to the Patient and Relative Information Sheets and Consent Forms. These are updated in line with the changes to the protocol, as follows:

(i) the 'Tracking Parkinson's' common name for the study has been added.
(ii) clarification of what happens to data and samples if participant withdraws during the study, as well as the fact that this would not affect their future care, has been added.
(iii) information regarding the UK Tissue Bank has been added.

Tracked copies of the new versions, all Version 1.2 dated 28/10/11, attached.

Revised and tracked version of GP Letter, Version 1.1 dated 16/12/11, attached.

Additional documents attached - personality questionnaire (BFI Big Five Inventory, wearing off questionnaire, additional questions for constipation questionnaire, attached. Also attached are the Expression of Interest in the Tracking Parkinson's Study Form(Version 1.0 dated 28/10/11), Tracking Parkinson's Poster (Version 1.0 dated 18/12/11) Tracking Parkinson's Letter (Version 1.0 dated 18/12/11) and Parkinson's UK Tissue Bank - Donor Information Booklet.

Is this a modified version of an amendment previously notified and not approved?

◉ Yes ○ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

PRoBaND Protocol Version 1.2, dated 28 October 2011

Summary of changes made to PRoBaND Protocol Version 1.1, dated 27 April 2011

In an attempt to meet the Committee's comments regarding the lack of conciseness and adequacy of the information provided, explanations of the changes, which fall under five headings, are outlined below:

Items that have been added:

a. We wish to advise participants in the study (both patients and relatives) about the Parkinson's UK Tissue Bank (also known as the Brain Bank), firstly by giving them information about this separate project, and secondly by inviting their participation in the project. This is a separate study, which has ethics approval (MREC reference number 07/MRE09/72). It will be introduced to participants during the PRoBaND study (rather than at baseline). Participants in PRoBaND who are willing to take part in the Tissue Bank study will be consented separately.

b. We wish to add a 'Wearing off' questionnaire for patients. This is a short questionnaire that assesses the treatment response to anti-Parkinson medication. It will be performed once (Visit 6, 30 months) for patients diagnosed for less than three years; and once (Visit 2, 6 months) for patients with PD onset aged less than 50 years.

c. We wish to add a personality questionnaire, which was omitted in error for one category of patient (onset under 50 years). It will be performed once, at Visit 2 (6 months).

d. We wish to add some extra questions on bowel function, which relate to gastroparesis, to the constipation questionnaire that is already included in the study. These questions have been validated by the gastroenterology

team in University College London. They would be applied in both patients and relatives.

e. Invitation to study participation. We would like centres to be able to contact patients known to their service (by letter or phone) and/or to advertise the study by a mini-poster. Also, Parkinson's UK, the study funder would like a method for their members to express interest in being involved in the study. Accordingly, we have developed standard wording for these methods of informing potential participants.

f. We have added clarification of what happens to data and samples if the participant withdraws during the study, and the fact that this would not affect future care.

Items that have been removed:

a. 'Change in medication' has been removed as we will derive this from other data collected about medication.

b. 'Diagnostic factors' has been removed after baseline visits, as this does not require repetition.

c. One set of vital signs (blood pressure and weight) at 18 months has been removed, as the baseline and 36 month data is considered sufficient.

d. 'Parkinson's medical items' has been removed as this information will already be captured sufficiently under 'Parkinson's Rating Score'.

e. 'Diagnostic features' is not required for young-onset cases and has been removed.

Items that have been simplified:

a. The timing of the L-dopa challenge test has been moved to a fixed rather than variable time point.

b. The items 'QOL questionnaire' and 'Global quality of life' have been merged to one item called 'QOL questionnaires'. The content is unchanged.

c. 'Medical history' at the relatives' second visit has been simplified such that only a new diagnosis of Parkinson's disease needs to be recorded.

d. 'Functional and structural imaging' has been renamed as 'Scans', just for simplicity. There is no change to the prior approach of collecting data about the scans, which are performed for clinical reasons.

Items that have been updated or rephrased:

a. The new common name for the PRoBaND study is 'Tracking Parkinson's' which has been added to the running title, and elsewhere as appropriate.

b. Contact information for study personnel, the number of study centres, and the study timelines have all been updated.

c. In study flow chart 3, a visit was described as Visit 3 incorrectly and this has been corrected to Visit 2.

d. The paragraph commencing 'Clinical scoring will adopt common data elements of the …' on page 16 has been rephrased as it was considered potentially unclear. There is no change to the study processes from this.

e. The linkage of the PRoBaND study to similar cohort studies has been updated with more specific reference to the linked studies.

f. The description of blood bottles used in the study has been updated, as the colour of some tubes has changed.

g. The procedure for gene test results has been rephrased, for clarity (pages 24-25). There is no change to the processes of the study. This clarifies that patients who have already had a gene test related to Parkinson's disease, on clinical grounds, are still eligible for entry to the PRoBaND study.

h. The membership and the terms of reference for the Data and Biosample Access Committee have been updated. The membership of the Independent International Review Committee has been updated.

Items that have been reorganized: (e.g. timing of observations changed)

a. ‘Diagnostic features’ for recent onset cases have been moved from Visit 2 (6 months) to Visit 3 (12 months), and from Visit 5 (24 months) to Visit 6 (30 months). This change is redesigned to better capture changes over time in clinical features of Parkinson’s disease.

b. Autonomic features. The timing has been changed so that changes over repeated 18 month intervals can be calculated.

Changes to the Patient and Relative Information Sheets and Consent Forms. These are updated in line with the changes to the protocol, as follows:

(i) the ‘Tracking Parkinson’s’ common name for the study has been added.
(ii) clarification of what happens to data and samples if participant withdraws during the study, as well as the fact that this would not affect their future care, has been added.
(iii) information regarding the UK Tissue Bank has been added.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Protocol (tracked changes)	1.2	28/10/2011
Participant Consent Form : Relatives of patients with Parkinson's disease (tracked changes)	1.2	28/10/2011
Participant Consent Form : Patients diagnosed with Parkinson's disease at under 50 years of age (tracked changes)	1.2	28/10/2011
Participant Consent From: Patients diagnosed with Parkinson's disease in the past three years (tracked changes)	1.2	28/10/2011
Participant Information Sheet: Relatives of patients with Parkinson's disease (tracked changes)	1.2	28/10/2011
Participant Information Sheet: Patients diagnosed with Parkinson''s disease at under 50 years of age (tracked changes)	1.2	28/10/2011
Participant Information Sheet: Patients diagnosed with Parkinson's disease in the last three years (tracked changes)	1.2	28/10/2011
Donor Information Booklet MREC reference number 07/MRE09/72	1/2011	
GP Letter (tracked changes)	1.1	16/12/2011
Expression of Interest in the Tracking Parkinson's Study form	1.0	28/10/2011
Tracking Parkinson's letter	1.0	18/12/2011
Tracking Parkinson's poster	1.0	18/12/2011
Personality questionnaire (BFI Big Five Inventory		
Wearing off questionnaire		
Additional questions for constipation questionnaire		

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I confirm that the study sponsor has been notified of the proposed amendment.*
3. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Dr Donald Grosset on 19/12/2011 12:05.

Job Title/Post:	Consultant Neurologist
Organisation:	NHS:GG&C
Email:	d.grosset@clinmed.ac.uk

Date:.....