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 to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) 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 (or other human biological samples) and data (specific project only)
( ) Study limited to working with 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. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. 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)*

☑ 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?

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] National Information Governance Board for Health and Social Care (NIGB)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

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 living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living 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 it 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 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).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Dr	Donald	Grosset
Work Address	Southern General Hospital		
	1345 Govan Road		
	Glasgow		
PostCode	G51 4TF		
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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:	January 2012
Protocol reference (if applicable), current version and date:	GN11NE062 Version 1.2, 28/10/11
Amendment number and date:	Version 1.3, 12/02/2014

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.

Updating of contact information of responsible individuals within Protocol; addition of new appendix providing written information for patients attending study visist 4 (18 months) in preparation for the L-dopa challenge at study

visit 5 (24 months).

(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.

PRoBaND Protocol Version 1.3, dated 12/02/2014 - tracked changes;
PRoBaND (Tracking Parkinson's) L-dopa test dose Guide Notes for patients, Version 1.0 dated 12/02/2014;
PRoBaND (Tracking Parkinson's) Relatives contact sheet Version 1.0 dated 12/02/2014 - tracked changes;
PRoBaND - Site record of patient contact re relatives, Version 1.0 dated 12/02/2014 - tracked changes;
PRoBaND (Tracking Parkinson's) - guide Notes for involving relatives in the study, Version 1.0, dated 12/02/2014 - tracked changes.

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.

1. A guide sheet for patients in preparation for the L-dopa challenge which is scheduled for Visit 5 (24 months) has been prepared. This does not involve any alteration in the protocol but has been prepared to streamline the process and provide patients with written guidance about what they should do prior to attending visit 5.

2. Recording sheets for inviting relatives to participate in the study, via the patient. The protocol specifies that patients who are selected to invite their relatives to participate in the study, should be asked to speak to their first degree relatives (brothers and sisters) and ask if they would be willing to take part in the study. There is no change to the protocol for this item. However, the recording sheets for collecting this information have been added so that the process of this discussion and its outcome can be documented and standardised at each study centre.

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*
PRoBaND (Tracking Parkinson's) - Protocol	1.3	12/02/2014
PRoBaND (Tracking Parkinson's) - L-dopa test dose Guide Notes for patients	1.0	12/02/2014
PRoBaND (Tracking Parkinson's) - Guide notes for involving relatives in the study	1.0	12/02/2014
PRoBaND (Tracking Parkinson's) - Relatives contact sheet	1.0	12/02/2014
PRoBaND - site record of patient contact regarding relatives	1.0	12/02/2014

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 consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Dr Donald Grosset on 24/04/2014 15:25.

Job Title/Post:	Consultant Neurologist/Chief Investigator
Organisation:	PRoBaND
Email:	d.g@talktalk.net

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Erica Packard on 25/04/2014 07:41.

Job Title/Post:	Research Co-ordinator
Organisation:	NHS Greater Glasgow and Clyde
Email:	erica.packard@ggc.scot.nhs.uk