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 complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

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)*

- [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 applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [ ] IRAS Form
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

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

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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

◉ Yes ○ No

5c. You have indicated that your study has sites located in England. For the research sites located in England, do you wish for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details

○ 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 Confidentiality Advisory Group 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	Queen Elizabeth University Hospital		
	1345 Govan Road		
	Glasgow		
PostCode	G51 4TF		
Email	donaldgrosset@gmail.com		
Telephone	01412012486		
Fax	01412327626		

For guidance on this section of the form refer to the guidance

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

International Standard Randomised Controlled Trial Number (ISRCTN):	None
ClinicalTrials.gov Identifier (NCT number):	Pending

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	Research and Development Department
Date study commenced:	14/11/11
Protocol reference (if applicable), current version and date:	Version 1.4, 19/02/15
Amendment number and date:	Amendment 1.7, 19/01/2017

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.

Version 1.5 24/06/16 is attached. Changes are shown in a TRACKED version, and a CLEAR version is also 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.

1. Participant Information Sheet Relatives EXTENSION Version 1.3 27.06.2016 TRACKED
Participant Information Sheet Relatives Version EXTENSION 1.3 27.06.2016 CLEAR
2. Participant Information Sheet Patient EXTENSION Version 1.2 27.06.2016 TRACKED
Participant Information Sheet Patient EXTENSION Version 1.2 27.06.2016 CLEAR
3. ICF Relatives EXTENSION Version 1.4 27.06.2016 TRACKED
ICF Relatives EXTENSION Version 1.4 27.06.2016 CLEAR
4. ICF Patients EXTENSION Version 1.2 27.06.2016 TRACKED
ICF Patients EXTENSION Version 1.2 27.06.2016 CLEAR

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.

This is an extension to the study, for an additional 4-year period from November 2016 to November 2020, for patients with Parkinson's disease of recent onset who have reached the end of the initial duration of participation (3 years), or the end of the interim extension period (ie. 4.5 years of participation). It is also an extension for siblings of patients with Parkinson's disease. Patients and siblings will be eligible if they have completed the previous visits and have capacity to consent to these additional visits. The purpose of the changes is
(a) to continue observations of the changes over time to document progression in Parkinson's, and the emergence of any prodromal features of Parkinson's in siblings. The significance is to capture longitudinal data during mid-stage Parkinson's, when motor and cognitive complications emerge.
(b) to offer genetic counselling and the option of NHS gene tests, for participants whose research analysis of DNA indicates a likely mutation or variation linked to the development of Parkinson's. This is significant as new treatments are under development, which specifically target mechanisms linked to genetic drivers of Parkinson's, ie. it is becoming important for people to know if they have a gene fault that is linked to Parkinson's.
The study protocol has been developed following review by the independent International Review Panel appointed by Parkinson's UK, and has also been formally reviewed by the Cohort Studies Council of Parkinson's UK (including movement disorder, neurodegenerative, and epidemiological experts) and has been developed with patient and public involvement, and has also has been reviewed by a lay panel, for content and design.

We have introduced two new documents: Information about research results Patients V1.0 27/06/2017, and Information about research results Relatives V1.0 27/06/2017. This is because we are anticipating new treatments becoming available in future, to treat specific genetic types of Parkinson's. Therefore, we feel that informing participants of the gene changes is important as it may change treatment in future.

Also, during the term of the study, a number of Principal Investigators have left the study. A list of PI changes has been prepared and attached for approval.

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	1.5	24/06/2016
Protocol CLEAR	1.5	24/06/2016
ICF Patients Extension TRACKED	1.2	27/06/2016
ICF Patients Extension CLEAR	1.2	27/06/2016
ICF Relatives Extension TRACKED	1.4	27/06/2016
ICF Relatives Extension CLEAR	1.4	27/06/2016
Participant Information Sheet Patient EXTENSION TRACKED	1.2	27/06/2016
Participant Information Sheet Patient EXTENSION CLEAR	1.2	27/06/2016
Participant Information Sheet Relative EXTENSION TRACKED	1.3	27/06/2016
Participant Information Sheet Relative EXTENSION CLEAR	1.3	27/06/2016
GP Letter of Recruitment Patient Extension TRACKED	1.2	27/06/2016
GP Letter of Recruitment Patient Extension CLEAR	1.2	27/06/2016
GP Letter of Recruitment Relative Extension TRACKED	1.2	27/06/2016
GP Letter of Recruitment Relative Extension CLEAR	1.2	27/06/2015
Information about research results Patients	1.0	27/06/2016
Information about research results Relatives	1.0	27/06/2016
Changes to Principal Investigators		18/01/2017
Letter of Award from Parkinson's UK		29/07/2016

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 15/03/2017 14:55.

Job Title/Post: Consultant Neurologist

Organisation:	NHS:Greater Glasgow & Clyde
Email:	donaldgrosset@gmail.com

Declaration by the sponsor's representative

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

This section was signed electronically by Ms Joanne McGarry on 15/03/2017 16:51.

Job Title/Post:	Research co-ordinator
Organisation:	NHSGG&C
Email:	joanne.mcgarry@ggc.scot.nhs.uk