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**The Oxford Parkinson’s Disease Centre (OPDC) Discovery Study:** Targeting the early pathological pathways in Parkinson’s disease

NRES Committee, South Central, Oxford A Research Ethics Committee

Reference number 16/SC/0108

[www.dpag.ox.ac.uk/opdc](http://www.dpag.ox.ac.uk/opdc)

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**Biosample and Clinical Data Application Form** Version 7, 08/APR/2024

Dear Researcher,

The OPDC Discovery study, established in 2010 with funding from the Monument Trust Discovery Award from Parkinson’s UK, is a wide-ranging multi-disciplinary research program designed to understand the earliest pathological pathways that give rise to Parkinson’s disease (PD). It has delivered one of the best-characterised clinical Parkinson's cohorts in the world, a new program in Parkinson's fMRI and laboratory biomarkers, a core expertise in molecular genetics and molecular neuropathology, the largest induced pluripotent stem cell (iPSC) research program in Parkinson's in Europe, and a world-leading research hub for the generation and deep phenotyping of transgenic rodent models of Parkinson's. From 2015 to 2026, in the third phase of our program we will direct increased knowledge of disease mechanisms to develop a translational research program aimed at changing clinical practice.

The OPDC Discovery cohort is a multi-centre UK natural history study recruiting participants from across the Thames Valley within 3.5 years of diagnosis. It links closely with the national ‘Tracking Parkinson’s’ programme, also funded by Parkinson’s UK. It includes analysis of participants’ DNA for some of the common gene mutations linked to Parkinson’s disease, as well as genome analysis approaches. The project also collects serum samples at baseline and longitudinally every 18 months for frozen storage, with detailed parallel clinical assessment from all patients with Parkinson’s disease. In addition, subjects with a sleep clinic diagnosis of REM sleep behaviour disorder (RBD), form the prodromal Parkinson’s at-risk group, being compared to age and gender matched control subjects at baseline and longitudinal visits. Baseline and longitudinal MRI brain scans (including structural and functional sequences acquired at 3.0 T) are being collected in a subgroup of control, PDand RBD subjects.

The DNA specimens, serum and skin samples are stored in the Nuffield Department of Clinical Neurosciences at the University of OxfordThe DNA and frozen biosamples are a valuable resource for scientists investigating the pathogenesis of Parkinson’s disease and related neurodegenerative disorders. The OPDC clinical consortium will make this material available where possible, although some samples are depleted and may not be available. Ideally, the collaborator will already hold specific ethical approval to store and analyse the requested anonymised samples, images and clinical information. If ethical approval is not held by the applicant, we would need to consider prospective application for this in specific cases. Following successful application, the biosample and clinical data will be released subject to payment and execution of a Material Transfer Agreement (MTA) or Data Transfer Agreement (DTA) between the relevant parties. A charge will be incurred for provision of data, scans or biosamples (see below). If work performed on the material supplied by OPDC is likely to generate future ideas, rights, processes or products of potential commercial value, the Institution where we are based will prospectively enter into a separate agreement between the external collaborating institution, Parkinson’s UK, and the University of Oxford on all relevant intellectual property arising.

It is a a condition of receiving data and/or samples that you return information such as results of assays, gene test studies, and similar, and the methods for obtaining derived variables such as with the clinical dataset, to the OPDC clinical consortium; except in the case where iPSc lines are deposited in a dedicated iPSc bank.

To initiate the application procedure please complete the request form and OPDC Discovery Cohort clinical data request form (excel format) and send it to us. If you have any further queries or want to discuss your requirements prior to filling out this form, please contact us viaemailParkinsons.discovery@nhs.net).

1. **Contact and Project Details**

Study PI Name:

Position:

Address:

Phone:

Facsimile:

E-mail:

Date requested:

Date needed:

Project Title:

Source of funding\*:

Ethical approval held for the study? Please circle: Yes No

Title of ethically approved study:

Name of awarding Research Ethics Committee (REC):

REC reference number:

Starting date of project:

Duration:

\*If this is not part of a peer reviewed grant application, please provide evidence of institutional support and/or peer review.

Additional co-investigators/ collaborators (both inside and outside of the PI’s primary institution:

**Lay summary (maximum 150 words):**

**Scientific justification:**

Please provide the necessary background, aims, justification for the type of sample or clinical/imaging information requested, sample size, analytical methods and number of cases requested from, techniques to be used, result of pilot studies (including relevant publications) and expected benefits to Parkinson’s disease research. This will be used to assess the value of the work against sample availability and is limited to 600 words maximum.

**2 Details of sample/clinical data requirement**

**A. DNA Samples**

Please describe proposed methods, and any specific requirements including minimum DNA quantity and concentrations

**B. Frozen Serum Samples**

The frozen serum samples are generally stored as 4-5 x 500 l aliquots per patient visit; the samples are stored at -80oC. Please describe the proposed usage and the volume of serum required for your project, which participant visit you require samples from and why (baseline, 18, 36, 54 months) and the number of times samples would be subjected to thawing and re-freezing. **Please note that baseline samples are now extremely precious and dwindling in supply,** therefore will only be made available if there is an overwhelming rationale to use these in preference to other visit samples.

**C. Clinical data**

A large amount of clinical anonymised information to assess motor, non-motor and cognitive function is currently collected at baseline and at longitudinal 18 monthly visits in control, PD, PD relative and RBD subjects. Study arms and visits requested are to be indicated in the table below. By default clinical data extracts for the PD arm exclude subjects who have received an alternate (i.e., non PD) diagnosis post recruitment and those who converted to be PD from other arms of the study (e.g., the RBD arm). Should you require data from the re-diagnosed subjects and/or the converters, please state this in the table below. A full data inventory and dictionary is provided alongside this application form (see OPDCDiscoveryCohort\_ClinicalDataRequest.xlsx). Please indicate all requested variables therein. Detailed instructions can be found at the top of the .xlsx file.

**D. Imaging data**

Baseline and longitudinal MRI brain scans (including structural and functional sequences acquired at 3.0 T) are being collected in a subgroup of control, PD, PD relative and RBD subjects at FMRIB (Functional MRI of the Brain: <http://www.fmrib.ox.ac.uk>).

**Please fully complete the below table specifying your requested participant numbers for each patient group for the related biosample/phenotypic or imaging data.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PLEASE COMPLETE ALL BOXES BELOW** | | | | |
|  | **PD Diagnosis < 3.5 years** | **Controls** | **PD Relatives** | **RBD subjects** |
| **Baseline DNA**  No. of participants? |  |  |  |  |
| **Frozen serum**  No. of participants?  Which visit (eg baseline, 18, 36, 54 months etc)? |  |  |  |  |
| **Clinical data**  No. of participants?  Which visit?  Please also complete: *OPDCDiscoveryCohort\_*  *ClinicalDataRequestForm V1.xlsx* |  |  |  |  |
| **MRI brain scans**  No. of participants?  Which sequences?  Which visit (eg baseline, 3 years)? |  |  |  |  |

*Funded by Parkinson’s UK. Parkinson’s UK is the operating name of the Parkinson’s Disease Society of the United Kingdom. A company registered in England and Wales (948776). Registered Office 215 Vauxhall Bridge Road, London SW1V 1EJ. A charity registered in England and Wales (258197) and in Scotland (SC037554).*

**OPDC Discovery Cohort- Data Access Charges for biosamples and cohort data**

Having made access to all biosamples, related phenotypic information and imaging data free to successful applicants from 2010 to 2020, we are introducing the below charges out of necessity which will be applicable from February 2020. These charges are on a par with similar organisational charges (UK Biobank, Imperial Tissue Bank) and will help fund the significant time incurred on the part of our biobank and database team in providing you with the necessary information and samples, as well as answer future related queries you may have. The charges will also cover the cost of shipping the related biosamples to your lab, and time incurred for the legal input for agreement of relevant Material Transfer Agreement (MTA) and Data Transfer Agreement (DTA). Costs will apply to all organisations including academic, charitable and commercially funded institutions.

* £800 + VAT per approved application that requires clinical phenotypic data in isolation, in up to 500 anonymised cohort subjects at single or multiple time points. Data in >500 subjects will be charged pro-rata.
* An additional cost of £1000 + VAT for data files which include “bulk data” (e.g genetic data, raw accelerometer data). Genetic data includes genotyping and imputed data. These costs are subject to change as and when more data are acquired costs may be increased.
* £1,000 + VAT per application that requires MRI data where anonymization is required to remove facial features, for up to 190 patient datasets at a single time point. This cost includes matched anonymised clinical phenotypic data. MRI Data from >190 subjects, or from the same subjects at multiple time points will be charged pro-rata.
* £1,000 + VAT per application that requires biosamples including DNA, serum, plasma, spinal fluid and skin fibroblasts in up to 190 subjects at a single time point. Biosamples in >190 subjects, or for the same subjects at multiple time points will be charged pro-rata. This cost includes matched anonymised clinical phenotypic data.
* £bespoke quote for re-contact requests
* -£bespoke quote for particularly time consuming customisation of datasets.

**Process and Timelines**

1. Applicants will need to complete and submit the OPDC Data Access Form which is available on the OPDC website ([www.dpag.ox.ac.uk/opdc/research/external-collaborations](file:///\\TIBIA1\DPAG\Wade-Martins_Group\WadeMartinsAdmin\OPDC\OPDC%20Website\Collaborate\www.dpag.ox.ac.uk\opdc\research\external-collaborations)), under OPDC Research and External Collaborations.
2. All OPDC Data Access applications will be reviewed by the OPDC Data Access Panel and a decision made and communicated to the applicant within 1 month of receipt.
3. On approval, a DTA and/or MTA (as appropriate) will be provided. The DTA and/or MTA should be reviewed and approved by the applicant’s research contracts/legal office and signed by an authorised representative.
4. Payment will be required (through completion of an invoice request form and generation of a related purchase order by the applying institution **before any work is performed**) in addition to a signed approved DTA/MTA, before any data or samples can be released to the applying institution.
5. We aim to provide data-only and “bulk data” files applications within 1 month of receipt of payment and a valid DTA/MTA. MRI and biosample requests will be provided within 6 weeks of payment receipt and a valid DTA/MTA.