

# **NINDS Parkinson's Disease Biomarkers Program Genetic, Genomic and Neuroimaging Data Use Agreement (DUA)**

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## **NINDS PDBP Genetic, Genomic, and Neuroimaging Data Use Agreement (DUA)**

**[Enter Requestor Study/Program name here, Requestor (PI) Name (First, Last)]**

### **1. Introduction and Statement of Policy**

The National Institutes of Health (NIH) has developed central data repositories to archive and distribute the results of studies provided by Contributing Investigators funded under NIH funds and others. Implicit in the establishment of the NIH data repositories, for example, the Parkinson's Disease Biomarkers (PDBP) Data Management Resource (DMR) is the view that scientific progress in this area will be greatly enhanced if the data produced by these studies are readily available to all investigators in the research community.

Dataset access will be provided to research investigators who, along with their institutions, have certified their agreement with the expectations and terms of access detailed below. It is the intent of the NIH and NINDS that Approved Users of PDBP DMR-provided datasets recognize any restrictions on data use delineated within the original informed consent agreements of contributing studies, as identified by the submitting institutions and stated on the DMR and other study websites.

Definitions of terminology used in this document are found in the Appendix.

The parties to this agreement include: the Principal Investigator (PI) requesting access to the study dataset ("the Approved User"), his/her home institution as represented by the Institutional Signing Official ("the Requester"), all collaborators on the PI's study, and the NINDS, NIH. The effective date of this agreement shall be the Access Approval Date.

#### **Terms of Access**

##### **1.1. Research Use**

The Requester agrees that if access is approved, the Principal Investigator named in the Data Access Request (DAR) submitted in the PDBP DMR, which should include the Information Technology Director or his/her designee, and any collaborator, trainee, or employee working on the proposed research project under the direct supervision of these individuals, shall become Approved Users of the requested dataset(s). Research use will occur solely in connection with the research project described in the DAR, which includes a description of the research objectives and design. New uses of these data outside those described in the DAR will require submission of a new DAR; modifications to the research project will require submission of an amendment to this application (e.g., the addition of new aims related to the approved project, and the potential addition of new PDBP or other datasets to an approved project). The Requester and all Approved Users may use the dataset(s) only in accordance with the parameters described on the PDBP DMR Web site for the appropriate research use, and any limitations on such use, of the dataset(s) and as required by law.

Research access to the requested dataset(s) is granted for a period of one (1) year as defined below. Contributing Investigators to the PDBP, or their direct collaborators at the same institution, who provided the data or samples used to generate a PDBP NINDS dataset and who have appropriate IRB approval, if applicable, for broader use of the data are exempt from the limitation on the scope of the research use as defined in the DAR. Note that individuals who are at different institutions need to submit their own request and signed DUA.

### **2. Institutional and Approved User Responsibilities**

The Requester agrees through the submission of the Data Access Request (DAR) that the PI named in the DAR has reviewed and understands the principles for responsible research use and data handling of the PDBP datasets as defined in the [NIH Data Sharing Policy](#) and the [NIH Genomic Data Sharing Policy](#) as detailed in this Data Use Agreement (DUA) and in the NINDS Parkinson's Disease

Biomarker Data and Biological Specimens Approved User Code of Conduct. The Requester and Approved Users further acknowledge that they are responsible for ensuring that all uses of the data are consistent with federal, state, and local laws and regulations and any relevant institutional policies. Through submission of the DAR, the Principal Investigator also agrees to submit annual data use reports to the appropriate PDBP Data Access Committee (DAC) via the DMR or as otherwise requested describing the research use of the Approved Users as described under "Research Use Reporting" below.

Additionally, all Approved Users must adhere to the PDBP Publications Policy.

Approved Users who may have access to personal identifying information for research participants in the original study at their institution or through their collaborators, may be required to have IRB approval. By approving and submitting the associated Data Access Request, the Institutional Signing Official provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including IRB approval if required. The Institutional Signing Official also assures through the approval of the Data Access Request that other organizations within the institution with relevant authorities have reviewed the relevant sections of the PDBP Data Sharing Policy and the associated procedures and are in agreement with the principles defined.

It is anticipated that, at least in some cases, these datasets will be updated with additional information. Unless otherwise indicated, all statements herein are presumed to be true and applicable to the access and use of all versions of these datasets.

### **3. Public Posting of Approved User's Research Use Statement**

The Principal Investigator agrees that, if he or she becomes an Approved User, information about the PI and the approved research use, including the submitted research description (abstract) and citations to all resultant publications may be posted on a public, US government web site. The information may include the Approved User's name and institution, project name, Research Use Statement, and a Non-technical Summary of the Research Use Statement. In addition, citations resulting from the use of PDBP biological samples and datasets may be posted on other NIH data repository websites.

### **4. Non-Identification**

Approved Users agree not to use the requested datasets, either alone or in concert with any other information, to identify or contact individual participants from whom data and biological samples were collected. This provision does not apply to research investigators operating with specific IRB approval, pursuant to 45 C.F.R. 46, to contact individuals within datasets or to obtain and use identifying information under an approved IRB research protocol. All investigators conducting "human subjects research" within the scope of 45 C.F.R. 46 must comply with the requirements contained therein.

### **5. Non-Transferability**

The Requester and Approved Users agree to retain control over the data and further agree not to distribute data obtained through this Data Access Request to any entity or individual not covered in the submitted Data Access Request. If Approved Users are provided access to datasets for inter-institutional collaborative research described in the Research Use Statement of the Data Access Request, and all members of the collaboration are also Approved Users through their home institution(s), data obtained through this Data Access Request may be securely transmitted within the collaborative group. All data security practices and other terms of use defined in this agreement and should follow guidelines as described in the DMR Best Security Practices for both the raw and the derived data, including any transmission of the data.

The Requester and Approved Users acknowledge responsibility for ensuring the review and agreement to the terms within this Data Use Agreement and the appropriate research use of PDBP data by research staff associated with any approved project, subject to applicable laws and regulations. PDBP datasets obtained through this Data Access Request, in whole or in part, may not be sold to any individual at any point in time for any purpose.

Approved Users agree that if they change institutions during the access period, they will submit a new Data Access Request and Data Use Agreement in which the new institution agrees to the PDBP data use policy before data access resumes. Any versions of data stored at the prior institution for the approved use will be destroyed and documented through a final Data Use Report as described below. However, if advance written notice and approval by the NINDS PDBP Data Access Committee is obtained to transfer responsibility for the approved research project to another Approved User within the same institution the data may not need to be destroyed.

## 6. Data Security and Data Release Reporting

The Requester and Approved Users, including the institutional Information Technology Director or his/her designee, acknowledge the intent of the NIH that they have reviewed and agree to handle the requested dataset(s) according to the those standards described in the current DMR Best Security Practices, including its detailed description of requirements for security and encryption. These include, but are not limited to:

- all Approved Users have completed all required computer security training required by their institution, for example, the <http://irtsectraining.nih.gov/>, or the equivalent;
- the data will always be physically secured (for example, through camera surveillance, locks on doors/computers, security guard);
- servers must not be accessible directly from the internet, (for example, they must be behind a firewall or not connected to a larger network) and unnecessary services should be disabled
- use of portable media, e.g., on a CD, flash drive or laptop, is discouraged, but if necessary then they should be encrypted consistent with applicable law;
- use of updated anti-virus/anti-spyware software;
- security auditing/intrusion detection software, detection and regular scans of potential data intrusions;
- use of strong password policies for file access.
- all copies of the dataset should be destroyed, as permitted by law, whenever any of the following occurs:
  - the DUA expires and renewal is not sought;
  - access renewal is not granted;
  - the NINDS requests destruction of the dataset;
  - the continued use of the data would no longer be consistent with the DUA.

In addition, the Requester and Approved Users agree to keep the data secure and confidential at all times and to adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to PDBP datasets. This agreement includes the maintenance of appropriate controls over any copies or derivatives of the data obtained through this Data Access Request.

Requesters and Approved Users agree to notify the NINDS Data Access Committee of any unauthorized data sharing, breaches of data security, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include the known information regarding the incident and a general description of the activities or process in place to fully define and remediate the situation. Within 3 business days of the NINDS Data Access Committee notification, the Requester, through the Approved User and the Institutional Signing Official, agree to submit to the NINDS Data Access Committee a more detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.

**All notifications and written reports of data security incidents should be sent to:**

NINDS Data Access Committee

[ninds-dac@mail.nih.gov](mailto:ninds-dac@mail.nih.gov)

The NINDS, the NIH, or another entity designated by the NIH may, as permitted by law, also investigate any data security incident. Approved Users and their associates agree to support such investigations and provide information, within the limits of applicable local, state and federal laws and regulations. In addition, Requesters and Approved Users agree to work with the NINDS and the NIH to assure that plans and procedures developed to address identified problems are mutually acceptable consistent with applicable law.

## 7. Intellectual Property

By requesting access to PDBP dataset(s), the Requester and Approved Users acknowledge the intent of the NIH that anyone authorized for research access through the attached Data Access Request follow the intellectual property principles within the PDBP Policy for Data Sharing as summarized below:

Achieving maximum public benefit is the ultimate goal of data distribution through the NIH PDBP data repositories. The NIH believes that these data should be considered as pre-competitive, and urges Approved Users to avoid making IP claims derived directly from the PDBP dataset(s). However, the NIH also recognizes the importance of the subsequent development of IP on downstream discoveries, especially in therapeutics, which will be necessary to support full investment in products to benefit the public.

It is expected that these NIH-provided data, and conclusions derived therefrom, will remain freely available, without requirement for licensing. The NIH encourages broad use of PDBP datasets coupled with a responsible approach to management of intellectual property derived from downstream discoveries in a manner consistent with the [NIH's Best Practices for the Licensing of Genomic Inventions](#) and the [NIH Research Tools Policy](#).

## 8. Research Dissemination and Acknowledgement of NINDS PDBP Study Datasets

It is the intent of the NIH to promote the dissemination of research findings from NIH funded datasets including the NINDS PDBP dataset(s) as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Approved Users are strongly encouraged to publish their results in peer-reviewed journals and to present research findings at scientific meetings, etc.

Approved Users agree to acknowledge the NINDS PDBP DMR, the Contributing Investigator(s) who contributed the data (and samples from his/her original study), and the primary funding organization that supported the contributing study in all oral and written presentations, disclosures, and publications resulting from any analyses of the data.

All manuscripts should include the following in the Acknowledgements section: *"Data and biospecimens used in preparation of this manuscript were obtained from the Parkinson's Disease Biomarkers Program (PDBP) Consortium, supported by the National Institute of Neurological Disorders and Stroke at the National Institutes of Health. Investigators include: Roger Albin, Roy Alcalay, Alberto Ascherio, Thomas Beach, Sarah Berman, Bradley Boeve, F. DuBois Bowman, Shu Chen, Alice Chen-Plotkin, William Dauer, Ted Dawson, Paula Desplats, Richard Dewey, Ray Dorsey, Jori Fleisher, Kirk Frey, Douglas Galasko, James Galvin, Dwight German, Lawrence Honig, Xuemei Huang, David Irwin, Kejal Kantarci, Anumantha Kanthasamy, Daniel Kaufer, James Leverenz, Carol Lippa, Irene Litvan, Oscar Lopez, Jian Ma, Lara Mangravite, Karen Marder, Laurie Orzelius, Vladislav Petyuk, Judith Potashkin, Liana Rosenthal, Rachel Saunders-Pullman, Clemens Scherzer, Michael Schwarzschild, Tanya Simuni, Andrew Singleton, David Standaert, Debby Tsuang, David Vaillancourt, David Walt, Andrew West, Cyrus Zabetian, Jing Zhang, and Wenquan Zou. The PDBP Investigators have not participated in reviewing the data analysis or content of the manuscript."*

Prior to Journal publication the manuscript must be submitted to the PDBP Steering Committee (via [PD-Pubs@ninds.nih.gov](mailto:PD-Pubs@ninds.nih.gov)) who will verify within 5 days that the PDBP is appropriately acknowledged. If this time elapses without notice from the PDBP Steering Committee Representatives, authors may proceed with the paper.

Full citation of all published manuscripts should be provided to the Biomarkers Discovery Cohort upon publication of manuscripts.

## **9. Research Use Reporting**

To assure that NIH policies and procedures for PDBP data use are adhered to, Approved Users agree to provide to the NINDS Data Access Committee annual feedback on how these data have been used and any results that have been generated as a result of access to the data, including patents and publications. This information will be used by the NINDS Data Access Committee staff for program evaluation activities, and may be considered by the NINDS PDBP Governance committees as part of the NIH effort to provide ongoing oversight and management of all NINDS PDBP data sharing activities.

## **10. Non-Endorsement, Indemnification**

The Requester and Approved Users acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of NINDS PDBP data, the NIH, the NINDS Data Access Committee, and Contributing Investigators do not and cannot warrant the results that may be obtained by using any data included therein. The NIH, the NINDS Data Access Committee, PDBP, DMR, and all contributors to these datasets disclaim all warranties as to performance or fitness of the data for any particular purpose.

No indemnification for any loss, claim, damage or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that the NIH, as an agency of the United States, may be liable only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. 2671 et seq.

## **11. Termination and Violations**

This Data Use Agreement will be in effect for a period of one (1) year from the date the dataset(s) are made accessible to the Approved User ("Approved Access Date"). At the end of the access period, Approved Users agree to destroy all copies of the requested dataset(s), except as required by publication practices or law to retain them.

Consideration will be given to a renewal of this agreement upon submission of a new DAR. Copies of NINDS PDBP dataset(s) may not need to be destroyed if, with advance notice and approval by the NINDS Data Access Committee, the project has been transferred to another Approved User. In this case, documentation must be provided that other Approved Users are using the dataset(s) under an active DAC approved research project at the same institution.

The Requester and Approved User acknowledge that the NIH or the NINDS may terminate this agreement and immediately revoke access to all NINDS PDBP datasets at any time if the Requester is found to be no longer in agreement with the policies, principles and procedures of the NIH and the NINDS.

By submission of the attached Data Access Request and this Data Use Agreement, the Requester through the Institutional Signing Official attests to the Approved Users' qualifications for access to and use of NINDS PDBP dataset(s) and certifies their agreement to the NIH principles, policies and procedures for the use of the requested datasets as articulated in this document and as summarized in the PDBP DMR Approved User Code of Conduct, including the potential termination of access should a violation of any of these agreement terms be identified.

Requesters and the Principal Investigator further acknowledge that they have shared this document, the PDBP DMR Approved User Code of Conduct, and the NINDS PDBP data sharing policies and procedures for access and use of PDBP datasets with any Approved Users, appropriate research staff, and all other Key Personnel identified in the DAR.

Institutional Signing Officials acknowledge that they have considered the relevant NINDS PDBP policies and procedures, that they have shared this document and the relevant policies and procedures with appropriate institutional organizations, and have assured compliance with local institutional policies related to technology transfer, information technology, privacy, and human subjects research.

## Appendix

### Definitions of Terminology

**Annual Data Use Report:** A report submitted to the DAC on the anniversary of access approval summarizing the analysis of NINDS PDBP datasets obtained through the Data Access Request and any significant findings derived from the work.

**Approved User:** Post-DAC approval will include the PI, collaborators at the home institution who are named in the "Senior/Key Person Profile" portion of the DAR, and trainees or staff to these investigators.

**Contributing Investigator:** The researcher who submitted the PDBP dataset to PDBP DMR.

**Data Derivative:** any data including individual-level data or aggregate PDBP data that stems from the original dataset obtained through PDBP DMR. Excepted from this term is summary information that is expected to be shared through community publication practices.

**Data Management Resource, PDBP-aka DMR.**

**PDBP DMR Approved User Code of Conduct:** A short summary highlighting key principles and practices agreed to by all research investigators requesting access to NINDS PDBP data from PDBP DMR. The elements within the Code of Conduct reflect the Terms of Access in this Data Use Agreement (DUA). Failure to abide by the Code of Conduct as agreed to at the time a PDBP DMR Project Request is submitted may result in revocation of access to any and all approved data sets.

**Final Data Use Report:** A final report submitted to the DAC at the conclusion of the approved access period when no additional access is sought, or when leaving an institution. This report should summarize the analysis of PDBP study datasets obtained through the Data Access Request and any significant findings derived from the work.

**Information Technology Director:** Someone with the authority to vouch for the IT capacities at an institution, or higher-level division of an institution (e.g., the School of Medicine).

**Institutional Signing Official:** Someone with the authority to sign on behalf of the Requester and credentialed through the eRA system as such.

**Requester:** The home institution/organization for the Primary Investigator (PI) that will use the requested data.

**Senior/Key Persons:** Collaborators at the home institution.

## **NINDS Parkinson's Disease Biomarkers DMR Data Request Form**

As a condition of receiving the limited access dataset, the requesting investigator must agree to the following terms:

- These data will be used for research purposes only;
- The original study PI, the initial primary study publication, and the NINDS will be acknowledged in any publication derived from these data and that the requestor will work with original PI, as outlined in DMR Policy Documents.

**PLEASE ENTER DATA INTO HIGHLIGHTED FIELDS BELOW THEN SIGN THE LAST PAGE**

1. Requestor Principal Investigator information:

Name and title

Affiliation

Name of requestor organization

Email address

Telephone number

Fax number

2. Requestor's Authorized Institutional Business Official Information:

Name and title

Email address

Telephone number

Fax number

3. Source of Funding, period of funding for this project and Grant or project number:

NOTE: If requesting PI is not the PI of the funded project, provide the name and contact email address for that investigator.



By signing this form, I, \_\_\_\_\_, acknowledge that I will use the aforementioned data only for the purpose(s) that are described above. I understand that use of these data for any purpose other than what is specified above is prohibited. I also take responsibility for all collaborators at my institution that utilize the data and will ensure that they abide by the terms of this Data Access Request and Data Use Agreement.

My signature below acknowledges the above, and that I have reviewed the NINDS PDBP Data Use Agreement (DUA) and agree to the terms outlined therein.

\_\_\_\_\_  
Requestor's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Requestor's Authorized Institutional Business  
Official's Signature

\_\_\_\_\_  
Date