NINDS Parkinson's Disease Biomarkers Program Data Use Agreement (DUA)

NINDS PDBP DMR Data Use Agreement (DUA)

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 Program (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 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 Data Access Requester (the "Requester") requesting access to controlled-access data (also referred to as an "Approved User"), the Requester's home institution (the "Institutional Requester") as represented by the Institutional Signing Official (SO), and the NIH. The effective date for this agreement shall be the Access Approval Date.

Terms of Access

1.1. Research Use

If access is approved, the Requester named in the Data Access Request (DAR) submitted in the PDBP DMR, 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 prior approval by the NINDS Data Access Committee (PDBPDAC@ninds.nih.gov) and may require updates to the 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). Approved Users may use the dataset(s) only in accordance with the parameters described on the PDBP DMR website for the appropriate research use, and in accordance with 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. 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 and Institutional Requester agree through the submission of the DUA that the Approved User(s) named in this DUA have reviewed and understand the principles for responsible research use and data handling of the datasets as defined in the NIH Data Sharing Policy and the NIH Genomic Data Sharing Policy as detailed in this DUA and in the NINDS Parkinson's Disease Biomarker Data and Biological Specimens Approved User Code of Conduct. The Approved User(s) and Institutional Requester further acknowledge that they are responsible for ensuring that all uses of the data are consistent with federal,

state, Tribal, and local laws and regulations and any relevant institutional policies. Through submission of the DAR, the Requester also agrees to submit annual data use reports to the PDBP Data Access Committee (DAC) via the DMR or as otherwise requested describing the research use of the Approved User(s) as described under "Research Use Reporting" below.

Additionally, all Approved Users, including the Requester, 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 DAR, the SO provides assurance that relevant institutional policies and applicable federal, state, Tribal, or local laws and regulations (if any) have been followed, including IRB approval, if required. The SO also assures through the approval of the DAR that the relevant authorities of the institution 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.

Approved Users and the Institutional Requester acknowledge responsibility for ensuring the review and agreement to the terms within this Agreement and the appropriate research use of controlled-access data obtained through the DAR, subject to applicable laws and regulations. Approved Users agree that controlled-access data obtained through the DAR, in whole or in part, may not be sold to any individual at any point in time for any purpose.

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

Requesters who are contributing data to the PDBP DMR agree that, if he or she becomes an Approved User, information about the Requester 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 website. The information may include the Requester'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. Visit PDBP Data Sharing Policy for more information about the embargo period and data sharing.

4. Non-Identification

Approved Users agree not to use datasets obtained through the DAR, either alone or in concert with any other information, to identify or contact individual participants from whom data and/or biological samples were collected. These provisions do not apply to original data submitters operating with specific Institutional Review Board (IRB) or equivalent body approval, pursuant to 45 CFR 46, to contact individuals within datasets or to obtain and use identifying information under an IRB-approved research protocol. All Approved Users conducting human subjects research within the scope of 45 CFR 46 must comply with the requirements contained therein.

Approved Users and the Institutional Requester acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of controlled-access data accessed through the request, the NIH and Submitting Investigator(s) do not and cannot warrant the results that may be obtained by using any data included therein. NIH and all contributors to these datasets disclaim all warranties as to performance or fitness of the data for any particular purpose.

5. Certificate of Confidentiality

Certificates of Confidentiality (Certificate) protect the privacy of research participants by prohibiting disclosure of protected information for non-research purposes to anyone not connected with the research except in specific situations. The data that are stored in and shared through the data repositories accessed under this agreement are protected by a Certificate. Therefore, Approved Users, whether or not funded by

the NIH, who are approved to access a copy of information protected by a Certificate, are also subject to the requirements of the Certificate of Confidentiality and subsection 301(d) of the Public Health Service Act. Under Section 301(d) of the Public Health Service Act and the *NIH Policy for Issuing Certificates of Confidentiality*, recipients of a Certificate of Confidentiality shall not:

> Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual whom the information, document, or biospecimen pertains; or
>
> Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.
>
> Disclosure is permitted only when:
>
> - Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
> - Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.
> - Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
> - Made for the purposes of other scientific research that is following applicable Federal regulations governing the protection of human subjects in research.
>
> For more information see: *Certificates of Confidentiality (CoC) | Grants & Funding*.

6. Non-Transferability

Approved Users and Institutional Requesters agree to retain control of datasets accessed through this request and further agree not to distribute controlled-access data to any entity or individual not identified in the approved DUA. If the Approved Users are provided access to datasets for inter-institutional collaborative research described in the Research Use Statement of the DAR, and all members of the collaboration are also Approved Users through their home institution(s) with active PDBP DMR accounts, data obtained through this DAR may be securely transmitted within the collaborative group. Approved Users and Institutional Requesters will follow all data security practices and other terms of use defined in this Agreement and the Institutional Requester's IT security requirements and policies. All data security practices and other terms of use defined in this agreement should follow guidelines as described in the NIH Best Security Practices for Controlled-Access Data and Repositories for both the raw and the derived data, including any transmission of the data.

Approved Users and the Institutional Requester acknowledge responsibility for ensuring the review and agreement to the terms within this DUA and the appropriate research use of PDBP data by all Approved Users associated with any approved project, subject to applicable laws and regulations. Datasets obtained through the associated DAR, in whole or in part, may not be sold to any individual at any point in time for any purpose.

Requester agrees that if they change institutions during the access period, they will submit a new DAR and DUA 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 DAC (PDBPDAC@ninds.nih.gov) 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.

If a Requester moves to a new institution without completing the Project Close-Out process, the Institutional Requester must immediately notify the NINDS PDBP DAC so that the project may be closed out and the data are destroyed according to NIH Security Best Practices for Users of Controlled-Access Data.

7. Data Security and Data Release Reporting

Approved Users, as well as the Institutional Requester, acknowledge the intent of the NIH that all Approved User(s) have reviewed and agree to handle the requested dataset(s) according to the standards described in the current NIH Best Security Practices for Controlled-Access Data and Repositories, including its detailed description of requirements for security and encryption. These include, but are not limited to:

- Approved Users have completed all required computer security training required by their institution, for example, CITI program | Information Security training, or the equivalent;
- the data will always be physically secured (for example, through camera surveillance, locks on doors/computers, security guard, etc.);
- 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., 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.
    - For exceptions to the data retention policy, see point 10. Project Close-Out.

In addition, 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 ensure that only authorized individuals can gain access to datasets. This agreement includes the maintenance of appropriate controls of any copies or derivatives of the data obtained through this DAR.

The Requester and Institutional Requester agree that the Institutional Requester's IT security requirements and policies are sufficient to protect the confidentiality and integrity of the NIH controlled-access data entrusted to Approved Users.

Human subject data are protected and secured and may not be shared with unapproved users. Approved Users agree to review the Protecting Human Genomic Data when Developing Generative Artificial Intelligence Tools and Applications notice and agree that all data and models, including AI tools and models, generated with the controlled-access data from PDBP DMR will be deleted when the project is closed.

Requester and the Institutional Requester agree to notify the NIH Incident Response Team, the NINDS DAC (PDBPDAC@ninds.nih.gov), and the NIH Data Management Incident Notification inbox of data security incidents such as unauthorized data sharing, breaches of data security, or inadvertent data release that may compromise data confidentiality within 24 hours of when the incident is identified. For the NIH Incident Response Team, notifications can be made by phone (301) 496-4357; Toll Free Number (866) 319-4357 or TTY: (301) 496-8294 and can also be sent by email to NIHInfoSec@nih.gov or via the Report an Incident Link: https://irtportal.ocio.nih.gov. For the NIH Data Management Incident Notification inbox, email DMI_OER@mail.nih.gov.

Requester and the Institutional Requester agree to notify the NIH Data Management Incident Notification inbox and the NINDS DAC (PDBPDAC@ninds.nih.gov) of any terms of access violations, hereinafter referred to as data managements incidents (DMIs), within 24 hours of when the DMI is identified. For the NIH Data Management Incident Notification inbox, email DMI_OER@mail.nih.gov.

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 fully. Within three (3) business days of the notification, the Approved User or Institutional Requester agree to submit to the NIH DAC (PDBPDAC@ninds.nih.gov) and the NIH Data Management Incident Notification inbox a detailed written report including the date and nature of the event, actions taken to remediate the issue(s), and plans or processes developed to prevent future incidents, including specific information on timelines anticipated for action. Approved User(s) and Institutional Requester agree to provide documentation verifying that the remediation plans have been implemented. Repeated violations or unresponsiveness to NIH requests any results in further compliance measures affecting the Institutional Requester and/or the Approved User(s).

All notifications and written reports of data security incidents should be sent to:
NINDS PDBP DMR Data Access Committee
PDBPDAC@ninds.nih.gov

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

8. Intellectual Property

By requesting access to dataset(s), Approved Users and the Institutional Requester acknowledge the intent of the NIH that anyone authorized for research access through the associated DAR follow the PDBP Policy for Data Sharing and intellectual property principles 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 pre-competitive and urges Approved Users to avoid making IP claims derived directly from the 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 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: Final Notice and the NIH Research Tools Policy.

9. Research Dissemination and Acknowledgement of NINDS PDBP Study Datasets

It is the intent of the NIH to promote the dissemination of research findings from datasets, including the 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, for example.

Approved Users agree to acknowledge the NINDS PDBP DMR, the Contributing Investigator(s) who contributed the data (and/or 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, Steven Gunzler, Lawrence Honig, Xuemei Huang, David Irwin, Un Kang, Kejal Kantarci, Anumantha Kanthasamy, Daniel Kaufer, Horacio Kaufmann, Qingzhong Kong, James Leverenz, Allan Levey, Carol Lippa, Irene Litvan, Oscar Lopez, Jian Ma, Richard Mailman, Lara Mangravite, Karen Marder, Kelly Mills, Nandakumar Narayanan, Laurie Orzelius, Vladislav Petyuk, Judith Potashkin, Liana Rosenthal, Rachel Saunders-Pullman, Clemens Scherzer, Michael Schwarzschild, Nicholas Seyfried, Tanya Simuni, Andrew Singleton, David Standaert, Debby Tsuang, David Vaillancourt, Jerrold Vitek, David Walt, Andrew West, Cyrus Zabetian, and Jing Zhang. 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 (PD-Pubs@ninds.nih.gov) who will verify within five (5) days that the PDBP is appropriately acknowledged or request edits to the manuscript. If this time elapses without notice from the PDBP Steering Committee Representatives, authors may proceed with the submission.

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

10. Research Use Reporting

To ensure that NIH policies and procedures for PDBP data use are observed, Requester agrees to provide to the NINDS DAC (PDBPDAC@ninds.nih.gov) 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 through their DAR renewal process or Close-Out process. This information will be used by the NINDS DAC 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.

11. Project Close-Out

Should the Approved User(s) no longer wish to use datasets, this DUA may be terminated through mutual agreement (contact PDBPDAC@ninds.nih.gov to initiate this process) and constitute Project Close-Out. Similarly, if this DUA ends and another DUA is not submitted and accepted within three (3) months, the Approved User(s) will enter Project Close-Out proceedings.

Upon Project Close-Out, Approved Users and Institutional Requester agree to destroy all copies and versions of the dataset(s) retrieved from the PDBP DMR regardless of the storage medium or format in accordance with the NIH Security Best Practices for Users of Controlled-Access Data. However, the Requester may retain these data as necessary to comply with law, regulation, and government policy. Retention of data beyond the termination date of the DUA requires written approval from the PDBP DAC. A Requester and Institutional Requester who retain data for any of these purposes continues to be a steward of the data and is responsible for the management of the retained data in accordance with the Institutional Requester's IT security requirements and policies.

The data may not be used to answer any additional research questions, even if they are within the scope of the approved DAR, unless the Requester submits a new DAR and is approved by NIH to conduct additional research. If a Requester retains data for any of these purposes, the relevant portions of terms for Non-Identification, Certificate of Confidentiality, Non-Transferability, Data Security and Data Release Reporting, Intellectual Property, Non-Endorsement and Indemnification, Termination and Violations, and Termination and Data Destruction remain in effect after termination of this Agreement. These terms remain in effect until

the data are destroyed and Attestation of the destruction of all data has been provided by the SO to the PDBP DAC.

The Institutional Requester must have policies and procedures to ensure that the Requester completes the Project Close-Out process (See Termination and Data Destruction Provision) before moving to a new institution. If the Requester moves to a new institution without completing the Project Close-Out process, the Institutional Requester must immediately notify the PDBP DAC. A new DAR, with updated signatures from the appropriate SO, in which the Requester agrees to the DUA, must be approved by the PDBP DAR before controlled-access data may be re-accessed.

12. Non-Endorsement and Indemnification

Approved Users and Institutional Requesters acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of NINDS PDBP data, the NIH, the PDBP DAC, and Contributing Investigators do not and cannot warrant the results that may be obtained by using any data included therein. The NIH, the PDBP DAC, 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.

13. Termination and Violations

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

Approved Users and Institutional Requesters acknowledge that the NIH or the NINDS may terminate the DAR, including this Agreement, and immediately revoke or suspend access to all datasets at any time if Approved User(s) is/are found to be no longer in agreement with the terms described in this DUA, or the policies, principles and procedures of the NIH and the NINDS. NIH may apply for injunctive or other equitable relief before courts of competent jurisdiction as remedy for breach of the DUA, in addition to all other remedies available at law or in equity.

By submission of the associated DAR and this DUA, the Institutional Requester attests to the Approved Users' qualifications for access to and use of dataset(s) and acknowledges 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.

The Requester and SO further acknowledge that they have shared this document, the PDBP DMR Approved User Code of Conduct, and the NINDS PDBP Data Sharing Policy and procedures for access and use of datasets with any Approved User(s), appropriate research staff, and all other collaborators identified in the DAR.

The SO acknowledges that they have considered the relevant NINDS PDBP policies and procedures, that they have shared this DUA 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 datasets obtained through the DAR and any significant findings derived from the work.

Approved User: A user approved by the NINDS PDBP DAC to access one or more datasets for a specified period (not to exceed 12 months) and only for the purposes outlined in the Requester's approved Research Use Statement. Any staff members and trainees under the direct supervision of the Requester who are listed on the DUA are also Approved Users and must abide by the terms laid out in the DUA.

Collaborator: An individual whose identity has been validated and who is a permanent employee of their institution at a level equivalent to a tenure-track professor or senior scientist equivalent, but who is not under the direct supervision of the Requester submitting the DAR, who assists with the research project involving controlled-access data. Internal collaborators are employees of the same institution as the Requester. External collaborators are not employees of the same institution as the Requester and consequently must be independently approved to access controlled-access data.

Contributing Investigator: The researcher who submitted the dataset(s) or sample(s) to PDBP DMR.

Data Access Committee (DAC): NIH Data Access Committees (DACs) review and approve, or disapprove, requests from extramural and intramural researchers for proposed secondary research uses of datasets. NIH DACs are formed based on topic expertise and are not necessarily specific to an Institute, Center, or Office (ICO). You can contact the PDBP DMR DAC at PDBPDAC@ninds.nih.gov.

Data Access Request (DAR): A request submitted to the DAC for specific research use specifying the data to which access is sought, the planned research use, and the names of collaborators or lab members. The DAR is initially submitted by the Requester, with concurrence from their Institutional Signing Official.

Data Access Requester (Requester): The individual who prepares DARs, Project Renewals, and Project Close-Out documents. To be able to submit a DAR, a Requester must be a permanent employee of their institution at a level equivalent to, but not limited to, a tenure-track professor or senior researcher. This individual must have oversight responsibility for others named on the DAR who will be granted access to the data (known as Approved Users) and can be accountable for ensuring that all aspects of data usage align with the terms of the DUA and institutional policy. Requesters cannot be post-docs, trainees, or lab technicians. Upon approval of the DAR and acceptance of this DUA, the Requester becomes an "Approved User" as defined in this DUA, and all Approved Users must submit their own DAR to gain access to the datasets through 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 (DMR): The PDBP DMR is a collection of modular components that provide researchers with access to tools that allow for the collection and quality assurance of data in a standardized format. The DMR coordinates the assembly of de-identified data into a common database, enabling the query and distribution of aggregate data.

Data Use Agreement (DUA): This agreement between the Requester, the Institutional Signing Official, and all associated lab members or collaborators ("Approved Users"), and NIH regarding the terms associated with access of datasets and the expectations for use of these datasets.

Dataset: The use of the terms "dataset" and "data" throughout this DUA shall refer to any and all data accessed through the PDBP DMR. All data stored in the DMR is considered controlled-access and must be maintained and handled in a confidential manner in accordance with this DUA.

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 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 datasets obtained through the DAR and any significant findings derived from the work, as well as patents or publications resulting from the work.

Institutional Requester: The home institution or corporation of the Data Access Requester. The Institutional Requester is represented by the Institutional Signing Official (SO).

Institutional Signing Official (SO): The label, "Signing Official," refers to the individual that has institutional authority to legally bind the institution in grants administration matters; this individual is frequently credentialed through the eRA system as such. The individual fulfilling this role may have any number of titles in the institution but is typically located in its Office of Sponsored Research or equivalent. The Institutional Signing Official for the Requester reviews the DAR, Project Renewal, and Project Close-Out applications submitted by investigators and legally binds the institution to agree to adhere to the terms described in this Agreement if the application is submitted to NIH. The Institutional Signing Official for the institution enters the Data Submission Certification and signs on behalf of the Submitting Investigator(s) who has submitted data.

Project Close-Out: Termination of a research project that used controlled-access data from an NIH controlled-access repository, such as the PDPB DMR, and confirmation of data destruction when the research is completed and/or discontinued.

Project Renewal: Renewal of a Requester's access to datasets for a previously approved project.

Progress Update: Information included with the annual DAR renewal or Close-Out summarizing the analysis of datasets obtained through the DAR, as well as any publications or presentations derived from the work.

Research Use Statement: A brief description of the proposed research submitted by the Requester and reviewed by the DAC to ensure that the research is consistent with the use limitations of the requested dataset.

NINDS Parkinson's Disease Biomarkers DMR Data Request Form

As a condition of receiving the dataset(s), the Requester 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 Requester will work with original PI, as outlined in DMR Policy Documents.

By signing this DUA, the SO confirms that the Requester:

- Is a permanent employee of the institution;
- Has direct oversight of laboratory staff/trainees listed herein; and
- Is accountable for ensuring the DUA terms of access are followed

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

1. Requester (Principal Investigator/Senior Scientist)

   Name and title: _____

   Institution: _____

   Institutional email address: _____

   Telephone number: _____

2. Institutional Signing Official

   Name and title: _____

   Institutional email address: _____

   Telephone number: _____

List all lab members and/or collaborators at the **same institution** for this project below:

Full Name & Role	Institutional Email Address	Signature	Date

Note: all lab members and/or collaborators listed must maintain their own active PDBP DMR account before accessing or handling datasets.

By signing this form, I, the Requester, _____, 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 lab members and collaborators at my institution listed on this DUA and will ensure that they abide by the terms of the associated DAR and this DUA.

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.

Requester's Signature _____ Date _____

Institutional Signing Official's Signature _____ Date _____