Accelerating Medicines Partnership® Parkinson's Disease and Related Disorders (AMP® PD/PDRD) Data Use Agreement

The Data Access Requester (Requester) and Institutional Requester, as represented by the Institutional Signing Official (SO), request access to data available through the Accelerating Medicines Partnership® (AMP®) Parkinson's Disease and Related Disorders (AMP PD/PDRD) Knowledge Platform for scientific investigation, teaching, or the planning of clinical research studies and agree to the following terms:

1. Requester and SO acknowledge and agree that this AMP PD/PDRD Data Use Agreement (DUA) grants permission as set forth below to use the AMP PD/PDRD Knowledge Platform and data contained within and describes obligations with respect to the AMP PD/PDRD Knowledge Platform.
2. Requester acknowledges that the data contained in the AMP PD/PDRD Knowledge Platform includes data from the AMP PD program, the AMP PDRD program, and the Global Parkinson's Genetics Program (GP2). Requester acknowledges and agrees that this DUA describes Requester's rights and obligation with respect to data from all three programs, collectively referred to as "AMP PD Data" in this DUA, provided that Section 17 sets forth separate intellectual property policies for each data set.
3. Requester will have access to de-identified data. Requester agrees not to use AMP PD Data, either alone or in concert with any other information, to identify or contact individual participants from whom data and/or samples were collected. These provisions do not apply to original Submitting Investigators 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 Requesters conducting human subjects research within the scope of 45 CFR 46 must comply with the requirements contained therein. If Requester is in possession of any data that can be used, either alone or in combination with any other information, to re-identify any subjects, Requester will immediately notify the AMP PD Access and Compliance Team (AMP PDRD ACT) at act@amp-pdrd.org and the GP2 Access and Compliance Team (GP2 ACT) at act@gp2.org. *Notification must occur within 24 business hours after becoming aware of possession of such data.*
4. Requester will not attempt to directly contact the cohort Principal Investigators (PIs) or staff associated with the studies that are part of the AMP PD/PDRD and GP2 programs concerning additional information regarding individual subjects, provided that, for clarity, contacts that are not specifically related to individual subjects are permitted.
5. Requester will use the AMP PD/PDRD Knowledge Platform solely to access and analyze the AMP PD Data in accordance with this DUA.
6. Requester and SO will not disclose or use AMP PD Data beyond the permitted disclosures and uses outlined in this DUA. We will not sell, rent, lease, loan, or license AMP PD Data to any third party.
7. Requester will require anyone with whom Requester will share relevant AMP PD Data,

including others on their team and within the institution, to comply with this DUA by having them become an approved registered user of the AMP PD/PDRD Knowledge Platform and agreeing to these terms through signature on and acceptance of this DUA, as applicable*, prior to my sharing of the data*.

8. Requester may disclose AMP PD Data only to individuals who are registered users of the AMP PD/PDRD Knowledge Platform and have the appropriate data access approval for the data I am sharing.
9. Requester and SO will respond promptly and accurately to annual requests by the AMP PDRD ACT and the GP2 ACT to update application information.
10. Should Requester elect to use the Terra environment for analyses, Requester agrees to abide by the Terra terms of service developed by the Terra platform operators. Should Requester elect to use the Verily Workbench environment for analyses, Requester agrees to abide by the Verily terms of service developed by the Verily platform operators.
11. Should Requester elect to download AMP PD Data, the host institution accepts responsibility for the security of the downloaded data, as verified by the SO's signature on this DUA, for as long as the downloaded data is in existence. Requester will also provide documentation to the appropriate ACT (act@amp-pdrd.org and/or act@gp2.org) as to why Requester is downloading the data. Requester acknowledges that they will be responsible for all costs associated with the download. Requester and SO also acknowledge and agree that all obligations with respect to downloaded data as set forth in this DUA survive the expiration or termination of the DUA.
12. Requester and SO will retain control over the AMP PD Data and will use appropriate administrative, physical, and technical security safeguards to prevent use or disclosure of the AMP PD Data other than as provided for by this DUA.
13. Requester and SO will immediately report any inadvertent data release, including breach of data security or other data management incidents, to AMP PDRD ACT, act@amp-pdrd.org, and GP2 ACT, act@gp2.org. *Such reports must occur within 24 business hours of becoming aware of any inadvertent data release.*
    a. Requester and SO agree to notify the NIH Incident Response Team, the AMP PDRD DAC, 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-HELP (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.
    b. Requester and SO agree to notify the NIH Data Management Incident Notification inbox and AMP PDRD DAC of any terms of access violations, hereinafter referred to as data management 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.

c. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully. Within 3 business days of the notification, Requester and SO agree to submit to the AMP PDRD DAC and the NIH Data Management Incident Notification inbox a 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 future incidents, including specific information on timelines anticipated for action. Requester and SO agree to provide documentation verifying that the remediation plans have been implemented. Repeated violations or unresponsiveness to NIH requests may result in further compliance measures affecting the Institutional Requester and/or the Data Access Requester(s).

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

14. Requester and SO have reviewed the NIH's expectations set forth in the current NIH Security Best Practices for Users of Controlled-Access Data, and Requester agrees to manage AMP PD Data in accordance with these expectations as well as my institution's IT security requirements and policies.
15. Requester will contact AMP PDRD ACT, act@amp-pdrd.org, and GP2 ACT, act@gp2.org, if Requester suspect that AMP PD Data are improperly shared on the AMP PD/PDRD Knowledge Platform, if Requester is concerned that AMP PD Data shared on the AMP PD/PDRD Knowledge Platform are improperly or incompletely de-identified, or if Requester suspects unauthorized use of AMP PD Data. *Such contact shall occur within 24 business hours after becoming aware of any improper data storage.*
16. Requester will comply with any rules imposed by their institution and its institutional review board, as well as any Federal, State, and local laws and regulations, in each case, that apply to their use of AMP PD Data, provided such institutional rules do not conflict with the obligations owed by me under this DUA. In the presence of such an unresolved conflict, Requester will cease to use the AMP PD Data until a suitable resolution is identified and implemented, and the obligations of this DUA continue to prevail without hindrance.
17. Requester and SO acknowledge that the AMP PD and AMP PDRD programs and GP2 have separate intellectual property (IP) policies and agree as follows:
    a. Data from the AMP PD/PDRD programs were generated under and are subject to an existing arrangement that has the following AMP PD/PDRD Intellectual

Property Policy that states: "AMP PD/PDRD users agree not to file patent applications on research discoveries made using the AMP PD Data, except in the rare instance when a consensus of the Foundation for the National Institutes of Health (FNIH), the AMP PD/PDRD Steering Committee and the AMP Executive Committee agree that it is in the best interests of the partnership and public health to do so. Intellectual property developed under National Institutes of Health (NIH) awards are subject to applicable Federal law, regulation, and NIH policy." Accordingly, it is in the rare instance that the AMP PD/PDRD Steering Committee, through an approval protocol, will deem that it is in the best interest of the AMP PD/PDRD program and the public health to grant an exception. If an exception is granted, Requester and SO agree to grant the funding partners of the AMP PD/PDRD program a nonexclusive, worldwide, royalty-free, sublicensable license to use and/or disclose the intellectual property rights in and to the research discoveries made using the AMP PD Data for noncommercial research purposes.

b. GP2 has been established as a pre-competitive consortium. All rights to pre-existing IP that is used in connection with the GP2 data will remain with the owner of such IP. GP2 will not acquire any rights in or to any pre-existing IP or improvements thereto. Requester and SO agree not to file a patent application, copyright, or assert trade secrets or other IP on research discoveries (including improvements to pre-existing IP) made using data from GP2 (except that articles divulging research discoveries may be copyrighted). For example, if Requester creates or improves an algorithm using GP2 data, Requester will not claim IP on this algorithm. (An "improvement" is a modification to, variation of, or derivation from the original IP.) For more information, please email act@gp2.org.

18. Requester understands in accessing the AMP PD/PDRD Knowledge Platform Requester is not granted any intellectual property rights and Requester will not seek any right, title or interest in the clinical data, analysis results, or other intellectual property uploaded into the AMP PD/PDRD Knowledge Platform that are owned by other individuals or entities, without the express written consent of the individuals or entities who uploaded the information to the AMP PD/PDRD Knowledge Platform.
19. Requester agrees, subject to Sections 17 and 18 above, that all data and discoveries generated by me from analyses of AMP PD Data (collectively, the "Study Materials Results") will become and be deemed part of the public domain through the AMP PD/PDRD Knowledge Platform. Requester will not seek intellectual property protection of the Study Materials Results and will make the Study Materials Results freely available without charge to the research community through the AMP PD/PDRD Knowledge Platform.
20. By accessing the AMP PD/PDRD Knowledge Platform, Requester waives any and all claims against the AMP PD/PDRD and GP2 programs, the Foundation for the National Institutes of Health, Inc., the AMP PD/PDRD funding and research partners, and the GP2 funding and

research partners with respect to or arising from my use of the AMP PD/PDRD Knowledge Platform or the AMP PD Data.

21. It is the policy of the AMP PD/PDRD and GP2 programs to make analyzed data available to investigators as quickly as possible. Data analysis for the AMP PD/PDRD and GP2 programs are expected to take years as methods for data analysis to evolve. Therefore, Requester understands that any data and/or results that are accessed might be preliminary. Finally, because "preliminary data" will be posted on the database, in the event that Requester uses or downloads AMP PD Data for the purposes of analysis and future publication in the form of abstracts, manuscripts, or other publications, Requester will: (a) note in such abstracts, manuscripts, or other publications the defined version of the data used in my analysis and the date of download, (b) prior to my submission of any material for publication, check the AMP PD/PDRD Knowledge Platform to determine if updated data is available, and (c) if the data is updated, note in such material for publication that the data has been updated in the AMP PD/PDRD Knowledge Platform.
22. If Requester seeks to publish manuscripts incorporating AMP PD Data or Study Materials Results, Requester agrees to comply with the AMP PD/PDRD Publications Policy guidelines and/or the Publication Policy of the GP2 program, as applicable, including sending manuscripts to the AMP PD/PDRD Publications Committee (manuscript@amp-pdrd.org) and/or the GP2 Steering Committee for administrative review prior to publication of a final manuscript. The administrative review is conducted to ensure compliance with this DUA and does not constitute editorial control by the AMP PD/PDRD Publications Committee and GP2 Steering Committee.
23. In all manuscripts and presentations incorporating AMP PD Data or Study Materials Results, Requester will acknowledge the AMP PD/PDRD and/or GP2 program(s), AMP PD/PDRD and/or GP2 funders, and the relevant cohorts who provided data to the AMP PD/PDRD and/or GP2 programs, as applicable, by including language similar to the following:

Partner Acknowledgements:

> "Data used in the preparation of this article were obtained from the Accelerating Medicine Partnership® (AMP®) Parkinson's Disease (AMP PD) and Parkinson's Disease & Related Disorders (AMP PDRD) Knowledge Platform. For up-to-date information on the study, visit https://www.amp-pdrd.org.
>
> "The AMP® PD program is a public-private partnership managed by the Foundation for the National Institutes of Health and funded by the National Institute of Neurological Disorders and Stroke (NINDS) in partnership with the Food and Drug Administration (FDA), National Institute on Aging (NIA), Aligning Science Across Parkinson's (ASAP) initiative; Celgene Corporation, a subsidiary of Bristol-Myers Squibb Company; GlaxoSmithKline plc (GSK); The Michael J. Fox Foundation for Parkinson's Research (MJFF); AbbVie Inc.; Pfizer Inc.; Sanofi US Services Inc.; and Verily Life Sciences LLC.
>
> "The AMP® PDRD program is a public-private partnership managed by the

Foundation for the National Institutes of Health and funded by the National Institute of Neurological Disorders and Stroke (NINDS) in partnership with the Food and Drug Administration (FDA), National Institute on Aging (NIA), AbbVie Inc.; Aligning Science Across Parkinson's (ASAP) initiative; C_2N Diagnostics, LLC; CurePSP; GlaxoSmithKline plc (GSK); Denali Therapeutics Inc.; Laboratory Corporation of America Holdings (Labcorp); The Michael J. Fox Foundation for Parkinson's Research (MJFF); Sanofi US Services Inc.; and Verily Life Sciences LLC.

"ACCELERATING MEDICINES PARTNERSHIP and AMP are registered service marks of the U.S. Department of Health and Human Services."

AMP PD/PDRD Cohort Acknowledgements:

"Clinical data and biosamples used in preparation of this article were obtained from the (i) Michael J. Fox Foundation for Parkinson's Research (MJFF) and National Institutes of Neurological Disorders and Stroke (NINDS) BioFIND study, (ii) Harvard Biomarkers Study (HBS) and the Stephen & Denise Adams Center for Parkinson's Disease Research of Yale School of Medicine (CPDR-Y), (iii) National Institute on Aging (NIA) International Lewy Body Dementia Genetics Consortium Genome Sequencing in Lewy Body Dementia Case-control Cohort (LBD), (iv) MJFF LRRK2 Cohort Consortium (LCC), (v) NINDS Parkinson's Disease Biomarkers Program (PDBP), (vi) MJFF Parkinson's Progression Markers Initiative (PPMI), and (vii) NINDS Study of Isradipine as a Disease-modifying Agent in Subjects With Early Parkinson Disease, Phase 3 (STEADY-PD3) and (viii) the NINDS Study of Urate Elevation in Parkinson's Disease, Phase 3 (SURE-PD3).

"BioFIND is sponsored by The Michael J. Fox Foundation for Parkinson's Research (MJFF) with support from the National Institute for Neurological Disorders and Stroke (NINDS). The BioFIND Investigators have not participated in reviewing the data analysis or content of the manuscript. For up-to-date information on the study, visit www.michaeljfox.org/biofind."

"Genome sequence data for the Lewy body dementia case-control cohort were generated at the Intramural Research Program of the U.S. National Institutes of Health. The study was supported in part by the National Institute on Aging (program #: 1ZIAAG000935) and the National Institute of Neurological Disorders and Stroke (program #: 1ZIANS003154)."

"The Harvard Biomarker Study (HBS) is a collaboration of HBS investigators [full list of HBS investigators found at https://www.bwhparkinsoncenter.org/biobank] and funded through philanthropy and NIH and Non-NIH funding sources. The Stephen & Denise Adams Center for Parkinson's Disease Research of Yale School of Medicine is funded through philanthropy and NIH and non-NIH funding sources. The HBS and CPDR-Y Investigators have not participated in reviewing the data analysis or content of the manuscript."

"Data used in preparation of this article were obtained from The Michael J. Fox Foundation sponsored LRRK2 Cohort Consortium (LCC). The LCC Investigators have not participated in reviewing the data analysis or content of the manuscript. For up-

to-date information on the study, visit https://www.michaeljfox.org/biospecimens)."

"PPMI is sponsored by The Michael J. Fox Foundation for Parkinson's Research and supported by a consortium of scientific partners: [*list the full names of all of the PPMI funding partners found at* https://www.ppmi-info.org/about-ppmi/who-we-are/study-sponsors]. The PPMI investigators have not participated in reviewing the data analysis or content of the manuscript. For up-to-date information on the study, visit www.ppmi-info.org."

"The Parkinson's Disease Biomarker Program (PDBP) consortium is supported by the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health. A full list of PDBP investigators can be found at https://pdbp.ninds.nih.gov/policy. The PDBP investigators have not participated in reviewing the data analysis or content of the manuscript."

"The Study of Isradipine as a Disease-modifying Agent in Subjects With Early Parkinson Disease, Phase 3 (STEADY-PD3) is funded by the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health with support from The Michael J. Fox Foundation and the Parkinson Study Group. For additional study information, visit https://clinicaltrials.gov/ct2/show/study/NCT02168842. The STEADY-PD3 investigators have not participated in reviewing the data analysis or content of the manuscript."

"The Study of Urate Elevation in Parkinson's Disease, Phase 3 (SURE-PD3) is funded by the National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health with support from The Michael J. Fox Foundation and the Parkinson Study Group. For additional study information, visit https://clinicaltrials.gov/ct2/show/NCT02642393. The SURE-PD3 investigators have not participated in reviewing the data analysis or content of the manuscript."

GP2 Cohort Acknowledgement:

"Data used in the preparation of this article were obtained from Global Parkinson's Genetics Program (GP2). GP2 is funded by the Aligning Science Against Parkinson's (ASAP) Initiative and implemented by The Michael J. Fox Foundation for Parkinson's Research (www.gp2.org). For a complete list of GP2 members see www.gp2.org."

24. Requester will provide either (i) a copy of the manuscript upon its acceptance for publication or (ii) the full citation of all published manuscripts to the AMP PD/PDRD Publications Committee (manuscript@amp-pdrd.org) and the GP2 Steering Committee. Citations will be listed on the AMP PD/PDRD and GP2 websites and available to the public through PubMed.
25. Access to the GP2 data components is managed solely by the GP2 ACT, which may notify users of additional GP2-specific data usage requirements from time to time. Requester and SO agree to comply with all such GP2-specific requirements immediately

upon notification by the GP2 ACT representative. Requester and SO agree that continued use of GP2 data components after receipt of additional terms constitutes acceptance of those terms.

26. REQUESTER AND SO ACKNOWLEDGE AND AGREE THAT THE AMP PD DATA ARE PROVIDED AS IS AND NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE AMP PD DATA PROVIDED UNDER THIS DUA. THERE ARE NO WARRANTIES OR REPRESENTATIONS AS TO THE PURITY, ACCURACY, SAFETY OR USEFULNESS OF THE AMP PD DATA OR THAT THE USE OF THE AMP PD DATA WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT.
27. Requester and SO acknowledge and agree that this DUA will remain in effect for a period of one (1) year from the Effective Date and will automatically expire at the end of this period unless terminated earlier or renewed. For Project Renewals requiring a signature from an authorized SO, Requester understands that the renewal process will be initiated by communications from AMP PDRD ACT or GP2 ACT approximately one (1) month prior to the expiration date of this DUA, and Requester agrees to respond promptly to communications from AMP PDRD ACT and GP2 ACT. For other renewals, Requester understands that investigators should sign, date, and submit a new DUA electronically at www.amp-pdrd.org within one year of the Effective Date of this DUA. Failure to renew access within three (3) months after the expiration of this DUA constitutes Project Close-Out (see definition below).
28. Requester and SO acknowledge and agree that this DUA may be terminated by the AMP PDRD program or GP2 without cause by providing written notice to me or the institutional official identified below at the email address(es) provided below. The NIH may immediately revoke or suspend my access to all AMP PD data at any time if Requester is found to no longer be in compliance with the terms described in this DUA, or the policies, principles, and procedures of NIH. 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. Requester also understands that the DUA may be terminated Requester or SO by providing thirty (30) days written notice to AMP PDRD ACT, act@amp-pdrd.org, and GP2 ACT, act@gp2.org.
29. Requester and SO understand that failure to abide by the terms of this DUA will result in the immediate termination of their privileges to access the AMP PD Data through the AMP PD/PDRD Knowledge Platform and to use AMP PD Data that has been downloaded in accordance with Section 11 above.
30. Requester and SO agree that their institutional IT security requirements and policies are sufficient to protect the confidentiality and integrity of the NIH controlled-access data entrusted to me and all users listed on this DUA.
31. Requester and SO agree that information about themselves and the approved research use may be posted publicly on the repository website. The information may include name, institution, project title, and research use description. Citations of publications resulting from the use of controlled-access data obtained through the DAR may also be posted on the repository website.

32. Human subject data are protected and secured and may not be shared with unapproved users. Requester and SO agree to review the Protecting Human Genomic Data when Developing Generative Artificial Intelligence Tools and Applications notice. Requester and SO agree that all data and models, including AI tools and models, generated with the controlled-access data from the AMP PD/PDRD Knowledge Platform will be deleted when the project is closed.
33. Requester and SO agree to retain control of AMP PD Data accessed through this request and further agree not to distribute AMP PD Data to any entity or individual not identified in the submitted request. If Requester and SO are provided access to AMP PD Data for inter-institutional collaborative research described in the Research Use Statement of the DAR, and all members of the collaborations are also Requesters through their home institution(s), data obtained through the DAR may be securely transmitted within the collaborative group. Requester and SO will secure the data according to the NIH Security Best Practices for Users of Controlled-Access Data, the terms of this DUA, and their institutional IT security requirements and policies.

    Requester and SO acknowledge responsibility for ensuring the review and agreement to the terms within this DUA that apply to them and the appropriate research use of AMP PD Data obtained through the DAR, subject to applicable laws and regulations. Requester and SO agree that AMP PD 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.
34. Requester and SO acknowledge that although all reasonable efforts have been made to ensure the accuracy and reliability of AMP PD Data through this request, the NIH and investigator(s) who submitted the data 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. No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this DUA. Each party shall be liable for any loss, claim, damage, or liability that said party incurs because of its activities under this DUA, except that NIH, as an agency of the United States, may be liable only to the extent provided under the Federal Tort Claims Act, 28 USC 2671 et seq.
35. 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 DUA are protected by a Certificate. Therefore, the Requester, whether or not funded by the NIH, who are approved to access a copy of information protected by a Certificate, is 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:
    a. Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of 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

b. 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.

c. 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.

d. For more information see: *Certificates of Confidentiality (CoC) | Grants & Funding*.

36. Upon the expiration of GP2 data access, the Requester, SO, and all approved users are strictly required to adhere to the following deletion protocols: All copies and versions of individual-level datasets retrieved from the AMP PD/PDRD Knowledge Platform or derived from these data must be permanently destroyed across all storage mediums and formats, in accordance with the NIH Security Best Practices for Users of Controlled-Access Data. This protocol does not apply to non-identifiable results or summary-level files.
37. Upon AMP PD/PDRD Project Close-Out (see definition below), Requester and SO and all users named on this DUA agree to destroy all copies and versions of the dataset(s) retrieved from the AMP PD/PDRD Knowledge Platform regardless of the storage medium or format in accordance with the NIH Security Best Practices for Users of Controlled-Access Data. However, Requester may retain these data as necessary to comply with law, regulation, and government policy. A user who retains data for any of these purposes, and their SO, continue to be a steward of the data and are responsible for the management of the retained data in accordance with the IT security requirements and policies.

    a. The retained data may not be used to answer any additional research questions, even if they are within the scope of the approved data access request, unless Requester submits a new DUA and is approved by NIH to conduct additional

research. If Requester retains data for any of these purposes, the policies and procedures laid forth in this DUA remain in effect until the data is destroyed.

b. The SO must have policies and procedures to ensure that the Requester completed the Project Close-Out process before moving to a new institution. If Requester moves to a new institution without completing the Project Close-Out process, the SO must immediately notify the AMP PD DAC (ACT@amp-pdrd.org) 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. A new DAR, in which the new SO agrees to the DUA, must be approved by the AMP PD DAC before AMP PD Data may be re-accessed by the Requester.

38. Sections 3, 4, 6-8, 10-13, 16-26, and 29-37 of this DUA will survive expiration or termination of this DUA.

IN WITNESS WHEREOF, the Parties hereto have duly executed this DUA as of the Effective Date by their authorized representatives.

Data Access Requester (Principal Investigator/Senior Scientist)

Signature: _____

Name: _____

Title: _____

Date: _____

Email: _____

Phone: _____

Authorized Institutional Signing Official (on behalf of the Institutional Requester)

I confirm that the Requester is 1) a permanent employee of the institution; 2) has direct oversight of laboratory staff/trainees listed herein; and 3) Is accountable for ensuring the DUA terms of access are followed.

Signature: _____

Name: _____

Title: _____

Date: _____

Email: _____

Phone: _____

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

Full Name	Institutional Email Address	Signature	Date

Note: all lab members and/or collaborators (see definition below) listed must maintain their own active AMP PD/PDRD account.

Terms and Definitions

Approved User: A user approved by the NIH AMP PD Data Access Committee to access one or more datasets for a specific period 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 this DUA are also Approved Users and must abide by the terms laid out in this 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 Data Access Requester submitting the Access Request, who assists with the research project involving controlled-access data. Internal collaborators work at the same institution as the Data Access Requester. External collaborators are not employees of the Requester and/or do not work at the same location as the Data Access Requester and consequently must be independently approved to access controlled-access data.

Data Access Request (DAR): A request submitted to a DAC for a specific research use specifying the data to which access is sought, the planned research use, and the names of collaborators.

Data Access Requester (Requester): The individual who prepares DARs, Project Renewals, and Project Close-Outs. To be able to submit a DAR, the 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; have oversight responsibility for others named on the data access request who will be granted access to the data; 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.

Data Use Agreement (DUA): Terms of access that include how the data accessed should be secured and used by the Requester, those they directly supervise, and any collaborators listed. The Institution is represented by the Institutional Signing Official as a signatory to this DUA and agree to adhere to terms of access.

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

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. 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 reviews Access Request, 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 DUA if the application is submitted to the NIH.

NIH Data Access Committee (DAC): NIH DACs review and approve, or disapprove, requests from extramural and intramural researchers for proposed secondary research uses of controlled-access datasets. NIH DACs are formed based on topic expertise and are not necessarily specific to an Institute, Center, or Office (ICO).

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

Project Renewal: Renewal of a Requester's access to controlled-access datasets (AMP PD Data) for a previously approved project with options to add or remove datasets and collaborators, as well as updates to the Research Use Statement.

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(s).