NINDS PDBP DMR Data Submission Request (DSR)

Introduction and Statement of Policy

The Investigator listed below is submitting data to the Parkinson's Disease Biomarkers Program (PDBP) Data Management Resource (DMR) for scientific investigation, teaching, or the planning of clinical research studies and agrees to the terms/statements contained in the Terms of Access.

The parties to this agreement include: the Investigator and their Institution, as represented by the Institutional Signing Official (SO) and the NINDS, NIH.

Terms

1. The data was collected and is being submitted in a manner consistent with all applicable national, Tribal, and state laws and regulations as well as relevant institutional policies.
2. Expectations with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, as applicable, or as otherwise determined by the Submitting Institution, will be delineated at submission.
3. Metadata and supporting information, materials, and documentation to adequately describe and facilitate interpretation will be submitted to PDBP DMR at submission.
4. The relevant office(s) or component(s) of an institution with appropriate roles and expertise (such as an Institutional Review Board (IRB), Privacy Board, Human Research Protection Program (HRPP), or equivalent body) has reviewed my proposal for data submission and assures that:
    a. Submission for subsequent sharing and use of the data for research purposes is consistent with explicit limitations on subsequent use, such as those imposed by laws, regulations, policies, informed consent, and agreements, or as otherwise determined by the Submitting Institution.
    b. The submitted data has been de-identified to the extent required by the PDBP DMR, applicable laws, regulations, and NIH policies.
    c. Significant consideration has been considered regarding potential risks to individual participants and their families as well as groups or populations associated with data submitted to PDBP DMR and subsequent sharing.
5. I agree that information about myself and the approved research pertaining to submitted data/information may be posted publicly on the PDBP DMR website. This information may include my name, my Institution, the project name, and research summary. In addition, citations resulting from the use of PDBP DMR samples and datasets may be posted on other NIH data repository websites.
6. The data and related information to be submitted includes **identifiable, sensitive information**.
   ☐ YES ☐ NO
    a. IMPORTANT: Research in which identifiable, sensitive information is collected or used includes research that:
        i. Meets the definition of human subjects' research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46)), including exempt research except for human subjects research in which participant information cannot be identified or their identity cannot readily be ascertained, directly or through identifiers;
        ii. Is collecting or using human biospecimens that are identifiable or that have at least a very small risk of being used to deduce the identity of an individual;

iii. Involves the generation or use of individual level human genomic data from biospecimens, regardless of identifiability; or
iv. Involves any other information where there is at least a very small risk that a person could be identified.

7. The data and related information to be submitted is covered by a **Certificate of Confidentiality**.
☐ YES ☐ NO ☐ Not Applicable

   a. IMPORTANT: Note that research subject to the NIH Certificates of Confidentiality Policy that involves the generation, collection, or use of identifiable, sensitive information that is funded in whole or in part by NIH is automatically deemed to be issued a Certificate of Confidentiality (CoC). For more information, see the NIH Certificates of Confidentiality webpage.

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

Signatures

SUBMITTED AND AGREED TO BY:

Investigator (Principal Investigator/Senior Scientist)

Signature: _____

Name: _____

Title: _____

Date: _____

Email: _____

Phone: _____

Authorized Institutional Signing Official

Signature: _____

Name: _____

Title: _____

Date: _____

Email: _____

Phone: _____