

PPMI Data Access Guidelines

Introduction:

To accelerate Parkinson's disease biomarker and drug development, The Parkinson's Progression Markers Initiative (PPMI) is committed to the ideal of rapid and public reporting of study data. Study data will be publicly available on the data portal hosted by the Laboratory of Neuro-Imaging (LONI) as soon as possible, refreshed on a daily or weekly basis, when possible.

While almost all PPMI data is publicly available, without specific request, three types of data may be available with approval of the PPMI Data Access Committee. These are: 1) data that, if publicly disclosed, could compromise the privacy of research participants 2) data that could impede study objectives, and 3) data that, if publicly disclosed, could compromise the privacy or confidentiality of PPMI collaborators. Data that could reasonably be linked to individual participants is generally not available beyond individuals directly involved in the conduct of the study. This document describes principles under which data may not be publicly disclosed, provides a process for investigators outside PPMI to request non-public data, and catalogs currently restricted datasets.

Guidelines and Principles:

1. The default expectation is that all datasets will be made available in the PPMI data portal.
2. Frequency of occurrence of a particular event will not systematically be a consideration when determining if data should be restricted.
3. Information that poses a clear and immediate risk of identifying specific participants will be eligible to be restricted based on determination of the PPMI Executive Steering Committee (ESC). An example of such data would be genetic information from participants with SNCA duplication/triplication.
4. Information that has the potential to influence other assessments in PPMI (such as DaTscan results in the Prodromal cohort) may be restricted at the discretion of the ESC.
5. LONI will sequester data developed from the use of PPMI biospecimens for a standard period of 45 days. Investigators may petition the PPMI Executive Steering Committee (ESC) for a longer sequester period.
6. All data derived from a new data submission workflow will be temporarily restricted subject to initial quality control review, the adequacy of which will be evaluated collectively by the PPMI ESC, PPMI Statistics Core, and LONI.
7. The PPMI ESC may require LONI to temporarily or permanently sequester data, or to retract data of dubious quality. The PPMI ESC may make these data available upon request.
8. LONI/Image & Data Archive (IDA) is considered the repository of record for PPMI. All data will be stored at LONI and will be available via the LONI/IDA web portal or LONI/IDA-approved cloud transfer service. If an investigator has an approved request for restricted data which cannot be provided via either of these methods, it will be made available to the investigator through an alternative agreed-upon secure file transfer method (e.g., HIPAA-compliant encrypted file share).
9. Based on these guidelines, data will be placed into one of 4 tiers:
 - a. Tier 1: Publicly available, refreshed daily
 - b. Tier 2: Publicly available, pending either a pre-defined embargo (e.g., 45 days for biospecimen results) or investigator submission of an associated cloud transfer request form (e.g., raw WGS or digital sensor data)
 - c. Tier 3: Available to external investigators upon request, with the explicit approval of the PPMI Data Access Committee. To request access to Tier 3 data, email ppmi@michaeljfox.org 1) a



description of the specific requested Tier 3 data, 2) an overview of the intended use of data, 3) a brief synopsis of proposed analyses, and 4) the names of all members of the requesting research team. This information must be emailed in either a PDF or Word Document format. All requests must re-acknowledge the terms of the [PPMI Data Use Agreement](#), the requirement that data not be shared beyond investigators named in the request, and that data will only be used for the purpose described in the request. The PPMI Data Access Committee will review and adjudicate data requests within 30 days of receipt.

- d. Tier 4: Access restricted to the PPMI ESC and Statistics Core, and cannot be made available to external investigators (*Note: PPMI Biorepository Core receives a subset of datasets with full dates to support reconciliation against biorepository records. PPMI Statistics Core receives serialized data in place of full dates. No other internal or external PPMI groups receives data with full dates through LONI.*) The majority of Tier 4 data is information that could reasonably identify individual participants.

Restricted Datasets and Access Levels:

Dataset Description	Reason for Sequester	Access Level
Biospecimen analysis results, during 45-day embargo	Temporary, for data quality and data management purposes	Tier 2
Data from new data submission workflows	Temporary, for data quality and data management purposes	Tier 2
Verily Raw Device Data	File size transfer restrictions	Tier 2
Whole Genome Sequencing	File size transfer restrictions	Tier 2
Whole Exome Sequencing	File size transfer restrictions	Tier 2
RNA Sequencing	File size transfer restrictions	Tier 2
iPSC Assays from FOUND-IN PD	File size transfer restrictions	Tier 2
DaTscan results for prodromal participants, including genetic mutation carriers, hyposmic individuals, and individuals with RBD (DaTscan Analysis, SPECT Scan Information Source Document, and SPECT Visual Interpretation Results)	Impediment to study objectives	Tier 3
AV-133 results for prodromal participants, including genetic mutation carriers, hyposmic individuals, and individuals with RBD (AV-133 Subject Eligibility, AV-133 Imaging, AV-133 Analysis Data , and AV-133 Scan Source)	Impediment to study objectives	Tier 3
UPSIT results for prodromal participants	Impediment to study objectives	Tier 3
MRI Imaging Data Transfer	Impediment to study objectives	Tier 3



Dataset Description	Reason for Sequester	Access Level
Information Source Document		
alpha-Synuclein Seed Aggregation Assay (αSyn-SAA) results for prodromal, healthy control and NMC groups	Impediment to study objectives	Tier 3
Actual dates of activity	Participant privacy risk	Tier 4
Data from participants with SNCA duplication/triplication	Participant privacy risk	Tier 4
Records for participants with no Screening visit	Contains information not applicable to current processes	Tier 4
Recoded U Penn Assay Data	Participant privacy risk	Tier 4
DaTscan Visit Exceptions	Participant privacy risk	Tier 4
Deleted Image Listing	Participant privacy risk	Tier 4
FOUND RFQ Data (Internal)	Participant privacy risk	Tier 4
Biospecimen Project IDs	May contain information on biospecimen analyses for which data are not yet available at LONI	Tier 4
Center-Subject List (Internal)	Participant privacy risk	Tier 4
Subject Participation Status (Internal)	Participant privacy risk	Tier 4
Adverse Events – with Serial Numbers	Participant privacy risk	Tier 4
AV-133 Imaging – with Serial Numbers	Participant privacy risk	Tier 4
Clinical Labs – with Serial Numbers	Participant privacy risk	Tier 4
Consent and Enrollment – with Serial Numbers	Participant privacy risk	Tier 4
DaTscan Imaging – with Serial Numbers	Participant privacy risk	Tier 4
Features of REM Behavior Disorder – with Serial Numbers	Participant privacy risk	Tier 4
Florbetaben Eligibility – with Serial Numbers	Participant privacy risk	Tier 4
Florbetaben Imaging – with Serial Numbers	Participant privacy risk	Tier 4
Incidents – with Serial Numbers	Participant privacy risk	Tier 4
iPSC Subject Eligibility	Participant privacy risk	Tier 4
Laboratory Procedures – with Serial Numbers	Participant privacy risk	Tier 4
Notifications – with Serial Numbers	Participant privacy risk	Tier 4



Dataset Description	Reason for Sequester	Access Level
PD Features – with Serial Numbers	Participant privacy risk	Tier 4
RBD PSG Eligibility – with Serial Numbers	Participant privacy risk	Tier 4
Screening/Demographics – with Serial Numbers	Participant privacy risk	Tier 4
Signature Form – with Serial Numbers	Participant privacy risk	Tier 4
TAP-PD Kinetics Device Testing – with Serial Numbers	Participant privacy risk	Tier 4