

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. Two types of data that may not be publicly available. These are: 1) data that, if publicly disclosed, could compromise the privacy of research participants and 2) data that could impede study objectives. The guidelines in this document aim to: 1) describe data that may not be publicly disclosed; 2) provide guidelines for public data disclosure including a process for investigators outside PPMI to request non-public data; and 3) catalog currently sequestered 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 sequestered.
3. Information that poses a clear and immediate risk of identifying specific participants will be eligible to be sequestered 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 prodromal cohorts) may be sequestered at the discretion of the ESC.
5. The PPMI Bioinformatics Core 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. The PPMI ESC may require the PPMI Bioinformatics Core to temporarily or permanently sequester data or retract data of dubious quality. The PPMI ESC may make these data available upon request.
7. All data will be stored on the LONI data portal and will be available only via the portal.
8. Based on these guidelines, data will be placed into one of 4 tiers
 - a. Tier 1: Publicly available in real-time
 - b. Tier 2: Publicly available after a delay (typically less than 45 days)
 - c. Tier 3: Available to external investigators upon request to the PPMI ESC. To request access to Tier 3 data, email ppmi@michaeljfox.org with 1) specification of requested Tier 3 data, 2) intended use of data, and 3) brief synopsis of proposed analyses. All requests must 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 ESC will review data requests within 30 days of receipt.
 - d. Tier 4: Access restricted to the PPMI ESC and Statistics Core (*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.*)

Sequestered Datasets and Access Levels:

Dataset Description	Reason for Sequester	Access Level
DatScan results for prodromal participants including genetic, hyposmic, and RBD cohorts (DATScan Analysis (IND), SPECT Scan Information Source Document (IND), and SPECT Visual Interpretation Results (IND))	Impediment to study objectives	Tier 3
AV-133 results for prodromal participants, including genetic, hyposmic, and RBD cohorts (AV-133 Subject Eligibility, AV-133 Imaging, AV-133 Analysis Data (IND), and AV-133 Scan Source (IND))	Impediment to study objectives	Tier 3
MRI Imaging Data Transfer Information Source Document (IND)	Impediment to study objectives	Tier 3
alpha-Synuclein Seed Aggregation Assay (αSyn-SAA) results for prodromal and NMC groups	Impediment to study objectives	Tier 3
Digital sensor sub-study device data	Undergoing quality control (Note: Sequester expected to last >90 days)	Tier 3
Data from participants with SNCA duplication/triplication	Participant deidentification risk	Tier 4 (ESC & Stats Core)
Records for participants with no Screening visit	Contains information not applicable to current processes	Tier 4 (ESC & Stats Core)
Cell Line Requests	Biospecimen request confidentiality policy	Tier 4 (ESC & Stats Core)
Fluid Request	Biospecimen request confidentiality policy	Tier 4 (ESC & Stats Core)
Biospecimen Results (Internal)	45-day QC period	Tier 4 (ESC & Stats Core)
Recorded U Penn Assay Data	Includes sample tube numbers	Tier 4 (ESC & Stats Core)
DatScan Visit Exceptions	Includes full dates	Tier 4 (ESC & Stats Core)
Deleted Image Listing	Includes full dates	Tier 4 (ESC & Stats Core)
FOUND RFQ Data (Internal)	Includes full dates	Tier 4 (ESC & Stats Core)
Biospecimen Project IDs	May contain information on biospecimen analyses for which data are not yet available at LONI	Tier 4 (ESC & Stats Core)
Center-Subject List (Internal)	Contains PHI	Tier 4 (ESC & Stats Core)
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Dataset Description (cont.)	Reason for Sequester	Access Level
Subject Participation Status (Internal)	Participant deidentification risk	Tier 4 (ESC & Stats Core)
Submitted Manuscript Listing	Contains information on unpublished manuscripts	Tier 4 (ESC & Stats Core)
Adverse Events – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
AV-133 Imaging – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Clinical Labs – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Consent and Enrollment – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
DaTscan Imaging – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Features of REM Behavior Disorder – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Florbetaben Eligibility – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Florbetaben Imaging – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Incidents – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
iPSC Subject Eligibility	Contains PHI	Tier 4 (ESC & Stats Core)
Laboratory Procedures – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Notifications – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
PD Features – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
RBD PSG Eligibility – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Screening/Demographics – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
Signature Form – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)
TAP-PD Kinetics Device Testing – with Serial Numbers	Contains PHI	Tier 4 (ESC & Stats Core)