# Access to Data and Biospecimens Form

application INSTRUCTIONS and checklist

Submit this form as an attachment along with your other application documents to request access to the Michael J. Fox Foundation’s (MJFF) biospecimens. You can find more information on each of these cohorts on MJFF’s [Biospecimen page](https://www.michaeljfox.org/biospecimens) and our associated [Biorepository Inventory Catalogue](https://mjffbiobank.org/#!/biospecimens-and-data). Please note that all MJFF biosamples are frozen; fresh collection of biosamples for immediate shipment is not available. Available numbers listed are as of 6/24/2021. For all applications, please be sure to email [mjffbio@iu.edu](mailto:mjffbio@iu.edu) to gain access to the biosample catalog for latest sample availability and to view information on available de-identified clinical data for these studies.

Investigator Information

Principal Investigator Name:

(First Name Last Name, Suffix )

Institution:

Project Title:

Biospecimen Request Checklist

☐ This application information page (applicant information)

☐ Biospecimen Request (2 page maximum not including literature citation page, use template *below*)

☐ Sample request table (please fill in the number of subjects you are requesting on the relevant table(s) below (Please fill out one table for each cohort you are applying to access).

#### Research Plan

Use the following application template to create an executive summary of your research plan and limit your plan to no more than two pages. Submissions exceeding two pages will be rejected. References are optional and must also be limited to two pages. Please delete the instructional text in each box before submitting this form.

|  |  |
| --- | --- |
| COHORT RATIONALE | Briefly describe why the cohort you are applying for is best suited for your proposed studies. The question(s) being posed must be appropriate to the source of the biospecimens, how they were collected, prepared, analyzed, and stored; their age; and the phenotypic and other accompanying data. |
| BIOSAMPLES REQUESTED & SAMPLE MANAGEMENT | Briefly outline the number and type of samples from unique subjects requested in the above tables, including descriptions of subject characteristics (e.g., PD, control, any specific clinical variables) and required biosample parameters (e.g., method of collection, QC), if relevant. Include a clear justification for the number of samples requested by including power calculations. Include a clear justification for the volume of sample requested (only request the minimum volume needed for the study). If results from the proposed study will be combined with those obtained from other samples, include an explanation of how the requested samples will fit in with the overall study design. Address how the samples will be held, managed, and processed. |
| PROJECT DETAILS | Define the study hypothesis and describe the study design, including methods that will be used to test it. Describe the specific procedures by which the samples will be tested and analyzed, including relevant data or citations demonstrating experience with these techniques. Outline the power of the proposed study and anticipated size of a detectable effect. |
| SUBMISSION OF DATA | Investigators who are approved to access samples will be required to submit a report of completed analyses to MJFF. MJFF will deposit these analyses in a platform of MJFF’s choosing for use by the research committee after 90 days. Describe what data and results will be returned to MJFF and specify timelines for project completion and submission. |

Sample Request Overview

**24-Hour Biofluid Sampling Study**

The 24-Hour Biofluid Sampling Study was an MJFF-sponsored assay qualification study that collected CSF and blood over 26 hours at 11 different time points. These samples are especially useful for studies looking to evaluate diurnal fluctuations and can be utilized for assay development or validation, biomarker discovery, or replication/validation studies.

Phase 1 consisted of two identical study visits (collection periods) performed in 13 healthy volunteers 10-14 days apart while Phase 2 consisted of one collection period performed in 12 Parkinson's disease subjects and 6 healthy elderly volunteers. Samples were collected via lumbar and venous catheters. Blood and CSF samples were collected concurrently at 11 timepoints from time zero (within 30 minutes after catheterization) to 26 hours.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Heathy Volunteers (Ages 30-55)** | | | | **PD (Ages 41-65)** | | **Healthy Volunteers (Ages 43-69)** | |
|  | **Collection 1** | | **Collection 2** | | **Single Collection** | | **Single Collection** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **CSF (500 µL)** | 13 |  | 13 |  | 12 |  | 6 |  |
| **Plasma (500 µL)** | 13 |  | 13 |  | n/a | n/a | n/a | n/a |
| **Serum (500 µL)** | 13 |  | 12 |  | 12 |  | 6 |  |
| **Whole Blood (200 µL)** | n/a | n/a | n/a | n/a | 12 |  | 6 |  |

Available de-identified clinical data: measures of neurological function and severity of PD (Phase 2).

**DATATOP**

The Deprenyl and Tocopherol Antioxidative Therapy of Parkinsonism (DATATOP) trial, conducted by the Parkinson Study Group in the late 1980s, was a long-term placebo-controlled study on the effect of Deprenyl and tocopherol (a form of vitamin E) on the progression of early Parkinson’s in previously untreated subjects. Data were collected at baseline and at a follow-up visit, approximately 12-18 months later. *There are no matching controls as part of this cohort.* DATATOP samples are appropriate for biomarker discovery as well as biomarker replication/validation studies.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Baseline** | | **Endpoint** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** |
| **CSF (250 or 500 µL)** | 722 |  | 514 |  |
| **DNA (3 µg)** | 468 |  | n/a | n/a |
| **Serum (200 or 500 µL)** | 724 |  | 511 |  |

|  |  |  |
| --- | --- | --- |
| **Sample Type** | **Available** | **Requested** |
| **Serum PK (200 µL)** | 797 |  |
| **Urine (1 mL)** | 799 |  |

**PLEASE NOTE:** Baseline samples were collected off drug; samples at follow-up visits were collected on drug. Serum PK and urine samples were collected at several instances between baseline and endpoint.

Available de-identified clinical data: measures of neurological function, severity of PD, cognition, and mood.

**FS-ZONE**

Pioglitazone in Early Parkinson’s Disease (“FS-ZONE”) was a placebo-controlled Phase 2 study conducted by the University of Rochester of two dosages of oral pioglitazone for safety, tolerability, and efficacy in individuals with early Parkinson’s. Data and biological samples were collected at baseline, 16, and 44 weeks of follow-up. Plasma, RNA from blood, and urine are available from up to 217 FS-Zone participants. *There are no matching controls as part of this cohort*. FS-Zone samples are appropriate for pharmacodynamic/pharmacogenetic studies.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Baseline** | | **16 Weeks** | | **44 Weeks** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **Plasma (200 µL)** | 203 |  | 195 |  | 185 |  |
| **RNA (1 µg)** | 203 |  | 193 |  | 185 |  |
| **Urine (1 mL)** | 201 |  | 192 |  | 185 |  |

**PLEASE NOTE:** Baseline samples were collected off drug; samples at follow-up visits were collected on drug.

Available de-identified clinical data: measures of neurological function, severity of PD, cognition, and mood.

**SURE-PD 2**

The Safety of Urate Elevation in Parkinson’s Disease (SURE-PD 2) trial, conducted by the Parkinson Study Group, was a placebo-controlled Phase 2 dose-ranging trial of oral inosine to assess its safety, tolerability, and ability to elevate urate levels in blood and CSF in individuals with early Parkinson’s. Data and biological samples were collected at baseline and 3-, 6-, and 18-month follow-up. *There are no matching controls as part of this cohort*. SURE-PD 2 samples are appropriate for pharmacodynamic/pharmacogenetic studies.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Baseline** | | **3M** | | **6M** | | **18M** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **CSF (250 µL)** | n/a | n/a | 44 |  | n/a |  | n/a |  |
| **RNA (1 µg)** | 75 |  | n/a |  | 73 |  | 1 |  |
| **Serum (200 µL)** | n/a |  | 69 |  | n/a |  | n/a |  |
| **Urine (1 mL)** | 74 |  | 1 |  | 72 |  | 23 |  |
| **Whole Blood (200 µL)** | 74 |  | n/a |  | 74 |  | 24 |  |

**PLEASE NOTE:** Baseline samples were collected off drug; samples at follow-up visits were collected on drug. Urine and whole blood are also available from approximately 50 subjects at drug discontinuation/end of study drug visits.

Available de-identified clinical data: Measures of neurological function, severity of PD, cognition, and mood.

**SURE-PD 3**

SURE-PD 3 was a placebo-controlled, double-blinded Phase 3 interventional trial to assess the efficacy of oral inosine in early Parkinson’s. The study was concluded ahead of the original 2-year timeline due to lack of efficacy of the treatment on the primary outcome measure of disease progression. MJFF has supported blood sampling for future biomarker researcher in SURE-PD 3 subjects. Specimens were collected over several visits: at baseline, after up to 24 months of treatment, and 3 months (of washout) later (27M). *There are no matching controls as part of this cohort.* SURE-PD 3 samples are appropriate for pharmacodynamic/pharmacogenetic studies.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Baseline** | | **12M** | | **18M** | | **24M** | | **3 month**  **(washout, 27M)** | |
| **Sample Type** | **Available** | **Available** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **DNA (3 µg)** | 192 |  | n/a |  | n/a |  | n/a |  | n/a |  |
| **Plasma (200 µL)** | 265 |  | 14 |  | 40 |  | 223 |  | 187 |  |

**PLEASE NOTE:** Baseline samples were collected off drug.

Available de-identified clinical data: Measures of neurological function, severity of PD, cognition, and mood.

**LRRK2 Cohort Consortium (LCC)**

The LRRK2 Cohort Consortium (LCC) is comprised of three closed studies: the LRRK2 Cross-sectional Study, the LRRK2 Longitudinal Study, and the 23andMe Blood Collection Study. The LCC was an international multi-site effort to study individuals with idiopathic PD, healthy controls, LRRK2 mutation-positive Parkinson’s patients, and LRRK2 mutation-positive controls. The LCC was intended to provide a resource for the study of novel Parkinson’s biomarkers with the goal of addressing the relevance of the LRRK2 genetic pathway. Thus, use of the LCC samples are appropriate for biomarker discovery, optimization, validation, and disease progression studies, but requestors should provide rationale for evaluating LRRK2 genetic samples in their application.

**LRRK2 Cross-Sectional Study**

Samples for the LRRK2 Cross-sectional study were collected from over 1600 PD patients and 1200 non-PD controls at a single timepoint across multiple study sites, with samples of various types available from a subset of subjects. Of the subjects enrolled 822 PD patients and 722 non-PD control subjects carry a mutation in the LRRK2 gene.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **LRRK2+ PD** | | **LRRK2- PD** | | **LRRK2+ Healthy** | | **LRRK2- Healthy** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **CSF (200 µl)** | 29 |  | 39 |  | 40 |  | 37 |  |
| **Plasma (200 µl)** | 168 |  | 72 |  | 160 |  | 197 |  |
| **RNA (1 µg)** | 172 |  | 72 |  | 170 |  | 205 |  |
| **Serum (200 µl)** | 168 |  | 70 |  | 161 |  | 196 |  |
| **Urine (1 mL)** | 95 |  | 29 |  | 117 |  | 147 |  |
| **Whole Blood (200 µl)** | 168 |  | 71 |  | 164 |  | 204 |  |
| **DNA (3 µg)** | 146 |  | 43 |  | 126 |  | 184 |  |

Available de-identified clinical data: demographics, neurological history, medication history, MoCA, ADL, MDS-UPDRS, Hoehn and Yahr Stage, and sleep/REM Sleep Behavior Disorder questionnaire.

**LRRK2 Longitudinal Study**

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **LRRK2+ PD** | | | | | | | **LRRK2- PD** | | | | | | | | |
|  | **V02** | | **V03** | | **V04** | | **V02** | | | | **V03** | | | **V04** | |
| **Sample Type** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | | **Req** | **Avail** | | **Req** | **Avail** | | **Req** |
| **DNA (3 µg)** | n/a |  | n/a |  | 3 |  | n/a | |  | 3 | |  | n/a | |  |
| **Plasma (200 µl)** | 64 |  | 56 |  | 42 |  | 58 | |  | 42 | |  | 37 | |  |
| **RNA (1 µg)** | 65 |  | 56 |  | 41 |  | 58 | |  | 41 | |  | 36 | |  |
| **Serum (200 µl)** | 66 |  | 56 |  | 41 |  | 58 | |  | 41 | |  | 37 | |  |
| **Urine (1 mL)** | 47 |  | 38 |  | 30 |  | 40 | |  | 33 | |  | 21 | |  |
| **Whole Blood (200 µl)** | 64 |  | 56 |  | 41 |  | 55 | |  | 41 | |  | 36 | |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **LRRK2+ Healthy** | | | | | | | **LRRK2- Healthy** | | | | | | | | |
|  | **V02** | | **V03** | | **V04** | | **V02** | | | | **V03** | | | **V04** | |
| **Sample Type** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | | **Req** | **Avail** | | **Req** | **Avail** | | **Req** |
| **DNA (3 µg)** | n/a |  | 1 |  | n/a |  | n/a | |  | 3 | |  | n/a | |  |
| **Plasma (200 µl)** | 37 |  | 29 |  | 18 |  | 58 | |  | 48 | |  | 29 | |  |
| **RNA (1 µg)** | 41 |  | 33 |  | 17 |  | 59 | |  | 48 | |  | 29 | |  |
| **Serum (200 µl)** | 37 |  | 28 |  | 17 |  | 58 | |  | 47 | |  | 29 | |  |
| **Urine (1 mL)** | 34 |  | 26 |  | 15 |  | 46 | |  | 37 | |  | 22 | |  |
| **Whole Blood (200 µl)** | 34 |  | 29 |  | 18 |  | 56 | |  | 48 | |  | 29 | |  |

Available de-identified clinical data: demographics, neurological history, medication history, MoCA, ADL, MDS-UPDRS, Hoehn and Yahr Stage, and sleep/REM Sleep Behavior Disorder questionnaire.

**23andMe Blood Collection Study**

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **LRRK2+ PD** | | **LRRK2- PD** | | **LRRK2+ Healthy** | | **LRRK2- Healthy** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **DNA (3 µg)** | 41 |  | 17 |  | 130 |  | 14 |  |
| **Plasma (200 µl)** | 47 |  | 17 |  | 132 |  | 14 |  |
| **RNA (1 µg)** | 45 |  | 18 |  | 138 |  | 14 |  |
| **Serum (200 µl)** | 47 |  | 17 |  | 133 |  | 14 |  |
| **Whole Blood (200 µl)** | 42 |  | 17 |  | 130 |  | 14 |  |

Available de-identified clinical data: demographics, family history MDS-UPDRS, Hoehn and Yahr Stage, and UPSIT scores.

**LRRK2 PBMC & Urine Biobank**

The LRRK2 PBMC & Urine Biobank was an effort to establish a urine and PBMC repository with accompanying clinical data from a LRRK2 cohort. Study subjects include 30 individuals with iPD, 25 individuals with G2019S-associated PD, 25 unaffected individuals with the G2019S mutation, and 60 healthy controls.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume. If applying for this cohort, please be sure to indicate the number of cells you will require for study & how the PBMCs you have used for previous studies were collected. Note that these are frozen, not fresh PBMCs.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **LRRK2+ PD** | | **LRRK2- PD** | | **LRRK2+ Healthy** | | **LRRK2- Healthy** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **PBMCs**  **(1.5M or 3M cells/vial)** | 23 |  | 25 |  | 25 |  | 60 |  |
| **Urine (1 mL)** | 25 |  | 28 |  | 23 |  | 56 |  |

Available de-identified clinical data: demographics, measures of neurological function, severity of PD, clinical history, and cognition.

**BioFIND**

The Fox Investigation for New Discovery of Biomarkers (BioFIND) was a collaborative effort between MJFF and NINDS to enroll individuals with well-defined, moderately advanced Parkinson’s and neurologically healthy controls. Standardized protocols and processes were developed to ensure that BioFIND specimens and data would have ongoing utility in Parkinson’s biomarker research. Clinical data and biological samples were collected at eight sites across the United States. Biospecimen collection was performed at baseline and samples were drawn within 1-3 hours of most recent PD medication administration. Biospecimens collected when subjects were off their PD medications are available from a single follow-up visit 14 days later.

The study consisted of 122 individuals with moderately advanced PD and 101 healthy controls. BioFIND samples are appropriate for biomarker discovery as well as replication and validation studies.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **PD** | | | | **Control** | | | |
|  | **Baseline** | | **14 Day** | | **Baseline** | | **14 Day** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **Blood pellet**  **(250 µL)** | n/a |  | 107 |  | n/a |  | 93 |  |
| **CSF (200 µL)** | n/a |  | 108 |  | n/a |  | 83 |  |
| **DNA (3 µg)** | 122 |  | n/a |  | 101 |  | n/a |  |
| **Plasma (200 µL)** | 122 |  | 116 |  | 101 |  | 95 |  |
| **RNA (1 µg)** | n/a |  | 129 |  | n/a |  | 88 |  |
| **Saliva (200 µL)** | n/a |  | 23 |  | n/a |  | 27 |  |
| **Urine (1 mL)** | n/a |  | 27 |  | n/a |  | 28 |  |

**PLEASE NOTE:** Baseline samples were collected on PD meds; samples at follow-up visits were collected off PD meds.

Available de-identified clinical data: demographics, neurological history, medication history, MoCA, ADL, MDS-UPDRS, Hoehn and Yahr Stage, and sleep/REM Sleep Behavior Disorder questionnaires.

**Parkinson Associated Risk Study (PARS)**

PARS was designed to evaluate risk for developing Parkinson’s disease. Subjects have been followed over ten years.

The study includes 301 individuals over 50 years old without a diagnosis of PD or other neurological disorder at enrollment, with measures of neurological function, severity of PD, cognition, and mood are available. DNA, RNA, CSF, and plasma are available. PARS samples are appropriate for replication, validation, and progression studies, and requests should justify rationale for using prodromal samples.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Baseline** | | **Y2** | | **Y4** | | **Y6** | | **Y8** | | **Y10** | |
| **Sample Type** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** |
| **CSF (200 µL or 500 µL)** | 15 |  | 78 |  | 23 |  | n/a |  | 19 |  | 3 |  |
| **DNA (3 µg)** | 218 |  | 14 |  | n/a |  | n/a |  | n/a |  | n/a |  |
| **Plasma (200 µL)** | 295 |  | 264 |  | 171 |  | 63 |  | 99 |  | 50 |  |
| **RNA (1 µg)** | 103 |  | 157 |  | n/a |  | n/a |  | n/a |  | n/a |  |

Available de-identified clinical data: measures of neurological function, severity of PD, cognition, and mood.

**Systemic Synuclein Sampling Study (S4)**

The Systemic Synuclein Sampling Study (S4) was an observational clinical study to better understand the progression of Parkinson's disease by identifying the best biofluids and tissues for measuring the protein alpha-synuclein outside of the brain as a potential biomarker in people with PD. The subjects include 19 patients with early PD, 20 with moderate PD, 21 with advanced PD, and 21 healthy controls.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume. If requesting tissue, please indicate the number of subjects below and the number of sections required for your studies in the text of your application. *Note: Given S4’s focus on synuclein measures and assays, investigators requesting access to these samples must probing synuclein related biomarkers.*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Early PD** | | **Moderate PD** | | **Advanced PD** | | **Healthy Control** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **CSF (250 µL)** | 16 |  | 18 |  | 20 |  | 21 |  |
| **DNA (3 µg)** | 19 |  | 20 |  | 21 |  | 20 |  |
| **Plasma (200 µL)** | 19 |  | 20 |  | 21 |  | 21 |  |
| **RNA (1 µg)** | 19 |  | 20 |  | 21 |  | 21 |  |
| **Saliva (250 µL)** | 16 |  | 20 |  | 19 |  | 21 |  |
| **Serum (200 µL)** | 19 |  | 20 |  | 20 |  | 21 |  |
| **Whole Blood (200 µL)** | 19 |  | 20 |  | 21 |  | 21 |  |
| **Colon tissue** | 19 |  | 20 |  | 21 |  | 21 |  |
| **Skin tissue** | 18 |  | 20 |  | 21 |  | 21 |  |
| **Submandibular Tissue** | 18 |  | 20 |  | 18 |  | 20 |  |

**STEADY-PD III**

The STEADY-PD III study was conducted to establish efficacy of isradipine to slow progression of Parkinson’s disease disability as determined by the change in the total (Part I-III) Unified Parkinson Disease Rating Scale (UPDRS) score. A total of 366 subjects with early idiopathic PD not requiring dopaminergic therapy were enrolled into the study. De-identified measures of neurological function, severity of PD, cognition, and mood are available for study subjects. *There are no matching controls as part of this cohort.* Steady-PD III samples are appropriate for pharmacodynamic/pharmacogenetic studies.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below.

If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Isradipine** | | | | **Placebo** | | | |
|  | **Baseline** | | **Endpoint (36M)** | | **Baseline** | | **Endpoint (36M)** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **DNA (3µg)** | 155 |  | n/a |  | 155 |  | n/a |  |
| **Plasma (200 µL)** | 164 |  | 156 |  | 157 |  | 149 |  |

**PLEASE NOTE:**  Baseline samples were collected on PD meds; samples at follow-up visits were collected off PD meds.

**AVE-8112**

The multiple ascending dose study to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of AVE-8112 in patients with Parkinson’s Disease trial was conducted by MJFF in collaboration with Sanofi. This Phase 1B trial of Sanofi’s PDE4 inhibitor (for the treatment of cognitive impairment in Alzheimer’s patients) was terminated before recruitment was complete. Specimens are available from Cohort 1 (single dose) and Cohort 2 (ascending dose). This cohort is appropriate for assay development, biomarker discovery, or studies probing pharmacodynamics/pharmacogenetics. Specimens were collected at multiple visits and time-points over a 30-day period from 13 individuals with PD. *There are no matching controls.* DNA, plasma, and serum are available.

Please indicate the number of subjects you are requesting next to the appropriate biofluid below. If requesting more than one aliquot of fluid (aliquot volume is listed below), be sure to include justification for the proposed volume.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Placebo** | | | | | | | | | | | | |
|  | **Day -1** | | **Day 1** | | **Day 2** | | **Day 7** | | **Day 14** | | **Day 28** | |
| **Sample Type** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** |
| **DNA (3 µg)** | n/a |  | 2 |  | n/a |  | n/a |  | n/a |  | n/a |  |
| **Plasma (200 µL)** | 1 |  | 2 |  | 1 |  | 2 |  | 2 |  | 2 |  |
| **Serum (200 µL)** | 1 |  | n/a |  | 1 |  | 1 |  | 1 |  | 1 |  |
|  | **1mg** | | | | | | | | | | | | |
|  | **Day -1** | | **Day 1** | | **Day 2** | | **Day 7** | | **Day 14** | | **Day 28** | |
| **Sample Type** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** |
| **DNA (3 µg)** | n/a |  | 6 |  | n/a |  | n/a |  | n/a |  | n/a |  |
| **Plasma (200 µL)** | 3 |  | 6 |  | 4 |  | 6 |  | 6 |  | 6 |  |
| **Serum (200 µL)** | 2 |  | n/a |  | 3 |  | 3 |  | 3 |  | 3 |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **2mg** | | | | | | | | | | | | | | | | | | | | | | | |
|  | **D -1** | | **D1** | | **D2** | | **D4** | | **D7** | | **D8** | | **D11** | | **D12** | | **D13** | | **D20** | | **D34** | | **ET** | |
| **Sample Type** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** | **Avail** | **Req** |
| **DNA (3 µg)** | n/a |  | 4 |  | n/a |  | 1 |  | 1 |  | 2 |  | n/a |  | n/a |  | n/a |  | 1 |  | n/a |  | n/a |  |
| **Plasma (200 µL)** | 1 |  | 5 |  | 3 |  | n/a |  | 3 |  | 1 |  | 1 |  | 1 |  | 2 |  | 2 |  | 3 |  | 2 |  |

**PLEASE NOTE:** Baseline samples were collected on PD meds; samples at follow-up visits were collected off PD meds.

(Limited) de-identified clinical data available: measures of neurological function/severity of PD and demographics.

**cere-120**

The CERE-120 studies were Phase 1/2 Trials Assessing the Safety and Efficacy of Bilateral Intraputaminal and Intranigral Administration of CERE-120 (Adeno-Associated Virus Serotype 2 [AAV2]-Neurturin [NTN]) in subjects with idiopathic Parkinson’s disease. These trials were multicenter, randomized, double-blind, and sham surgery controlled. Specimens are available from CERE-120-01, CERE-120-03, and CERE-120-09. Specimens were collected at multiple visits. Limited clinical data are available from these trials. Serum is the only biofluid available. This cohort is appropriate for assay development, biomarker discovery, or studies probing pharmacodynamics/pharmacogenetics.

* CERE-120-01: 12 individuals with PD
* CERE-120-03: 62 individuals with PD
* CERE-120-09: 74 individuals with PD

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **CERE-120-01** | | | | | | | | | |
|  | **BL (Week 1)** | | **3M** | | **6M** | | **9M** | | **12M** | |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |
| **Serum (200 µL)** | 12 |  | 12 |  | 12 |  | 12 |  | 12 |  |
|  | **CERE-120-03** | | | | | | | | | |
|  | **18M** | | **24M** | | **30M** | | **Unknown** | |  |  |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |  |  |
| **Serum (200 µL)** | 5 |  | 2 |  | 1 |  | 57 |  |  |  |
|  | **CERE-120-09** | | | | | | | | | |
|  | **BL (1M)** | | **3M** | | **12M** | |  |  |  |  |
| **Sample Type** | **Available** | **Requested** | **Available** | **Requested** | **Available** | **Requested** |  |  |  |  |
| **Serum (200 µL)** | 73 |  | 54 |  | 54 |  |  |  |  |  |

**PLEASE NOTE:** Baseline samples were collected on PD meds; samples at follow-up visits were collected off PD meds.