



Parkinson's  
Progression  
Markers  
Initiative

***PPMI***

**Biospecimen  
Collection,  
Processing &  
Shipment Manual**

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## **1.0 Biorepository Information**

### **1.1 Biorepository Contacts**

#### **1.1.1 Indiana University Study Support**

Indiana University business hours are from 8 AM to 5 PM US Eastern Time, Monday through Friday.

#### **General Study Contact Information**

Phone: 317-274-5744

International Phone: (00+1) 317-274-5744

e-mail: [ppmibio@iu.edu](mailto:ppmibio@iu.edu)

Fax: 317-278-1100

#### **Sample Shipment Mailing Address**

PPMI Biorepository

Indiana University School of Medicine

351 W. 10th Street, TK-217

Indianapolis, IN 46202

#### **Staff Contacts**

Tatiana Foroud, PhD, Core Leader

Phone: 317-274-2218

Danielle Smith, BS, Project Manager

Phone: 317-274-5744

Karla Gonzalez, Clinical Research Coordinator

Phone: 317-278-1148

Cheyenne Herring, Clinical Research Technician

Phone: 317-278-1192

### 1.1.2 BioRep Study Support

BioRep business hours are from 8 AM to 7 PM Europe Central Time, Monday through Friday (and if necessary, on Saturday morning from 8 AM to 12 PM).

#### **Staff Contacts**

Paola Casalin, Project Manager

e-mail: [ppmi@biorep.it](mailto:ppmi@biorep.it)

Phone: +39 02 58029768

After Hours: +39 348 0716024

Fax: +39 02 58018471

Giulia Malferrari, Molecular Biology Laboratory Manager

e-mail: [ppmi@biorep.it](mailto:ppmi@biorep.it)

Phone: +39 02 58029725

After Hours: +39 348 0716025

Fax: +39 02 58018471

#### **Sample Shipment Mailing Address**

BioRep Srl

c/o DIBIT2 Palazzina San Michele Via Olgettina 60

20132 Milano – Italy

### 1.1.3 Tel Aviv Study Support

Tel Aviv business hours are from 8:30 AM to 5 PM (GMT+2), Sunday through Thursday.

#### **Staff Contact**

**Mali Gana-Weisz**

e-mail: [maliqw@tlvmc.gov.il](mailto:maliqw@tlvmc.gov.il)

Phone: 972-3-6947271, 972-3-6973628

Fax: 972-3-6973628

#### **Sample Shipment Mailing Address**

6 Weizmann St. (The Genetic Institute – R&D)

Tel Aviv 64239, Israel

## 1.2 Holiday Schedules

Please note that courier services may observe a different set of holidays. Please be sure to verify shipping dates with your courier prior to any holiday. Weekend/holiday delivery must be arranged in advance with the biorepository. Individual collection site questions should be directed toward the respective repositories.

**Frozen samples must be shipped Monday – Wednesday only.**

### 1.2.1 Holiday Observations – United States

Date
New Year's Day
Martin Luther King, Jr. Day
Memorial Day
Independence Day (observed on Friday if the holiday falls on a Saturday, and observed on Monday if it falls on a Sunday)
Labor Day
Thanksgiving Day and following Friday
Christmas Day (observed on Friday if the holiday falls on a Saturday, and observed on Monday if it falls on a Sunday)

Please note that between December 24th and January 2nd, Indiana University will be open Monday through Friday for essential operations ONLY and will re- open for normal operations on January 2nd. **If possible, biological specimens for submission to Indiana University should NOT be collected and shipped to Indiana University between December 24th and January 2nd.** If samples are collected during this holiday period and cannot be shipped, please store them at -70 or -80 degrees Celsius and ship them on dry ice to Indiana University AFTER January 1.

### 1.2.2 Holiday Observations – Europe

Date
1st January
6th January
Easter and Easter Monday
25th April
1st May
2nd June
15th August
1st November
7th and 8th December
25th and 26th December

### 1.2.3 Holiday Observations – Tel Aviv

Date
Purim
Passover
Memorial Day
Independence Day
Shavuot
Rosh Hashanah
Yom Kippur
Sukkot
Chanukah

## 2.0 Specimen Collection Kits and Supplies

### 2.1 Covance Clinical Lab Collection Kits

Clinical lab supplies will be provided to sites by Covance and will include all materials needed for collecting the clinical blood samples, as well as shipping materials except for dry ice for screening and baseline labs). These samples will be shipped to Covance after collection.

### 2.2 Covance Resupply

Automatic Resupply: Covance will anticipate the number of kits needed at each site and resupply based on the number of complete kits that have been shipped back to Covance. Please note that this service can result in extra kits being supplied to the sites to ensure appropriate kits quantities are on hand. Sites are responsible for actively monitoring inventory and expiration dates of kits and shipping materials. Should additional supplies be needed, a minimum of 10 working days is required for kit resupply. If you are located in an extended delivery area, your delivery may be longer. Please refer to the Covance Lab Manual or contact Covance if you have any questions.

## 2.3 Research Biospecimen Collection Kits and Supplies

Research specimen collection kits will be provided to sites by Indiana University. Kits will include most of the materials needed for biospecimen collection. Kits will include tube labels, which will be pre-printed with study information and the type of sample being drawn. It is important that you check to be sure that all tubes are properly labeled during processing and at the time of shipment. The kits will also include shipping labels and packaging necessary for sending samples back to the PPMI biorepository.

Each site is responsible for providing:

Dry Ice	Crushed Ice
Alcohol Prep Pads	Gauze Pads
Bandages and Steri-Strips	Butterfly Needles
Tourniquets	Tube Racks (2 mL to 10 mL)
Gloves	Sharps Bin and Lid
Pipettes and Pipette Tips	Lidocain for LP (Non-US Sites Only)
Lidocaine for skin biopsy (if performing)	Normal, non-sterile saline (if performing skin biopsy)

Sites shipping to BioRep will also obtain shipping materials through BioRep (see contact information in Section 1.1.2).

## 2.4 Research Specimen Collection Kit Contents

Research collection kits contain the items listed under each kit type (see Appendix E). Each kit provides the necessary supplies to collect samples from one subject. PPMI kit components have been carefully selected to suit the needs of this project. **Do not replace or supplement any of the tubes or kit components provided by Indiana University with your own supplies unless you have received approval from MJFF/Indiana University to do so.**

**Note:** “Supplemental” kits will be provided to sites should you require additional supplies from those contained in the visit specific kits.

## 2.5 Automatic Kit and Label Distribution

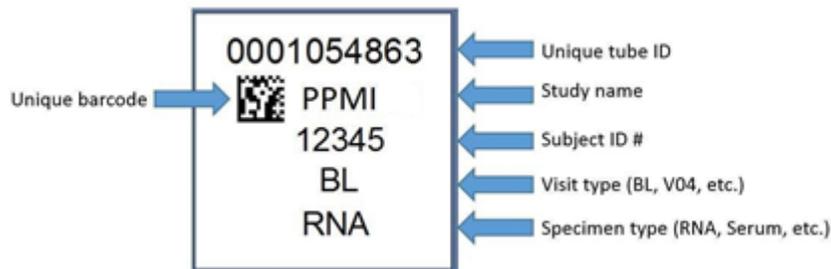
For subjects who have enrolled in the study and completed a BL visit, all kits (including study visit labels) for each subsequent subject visit will be sent to the site automatically. This is done according to the subject’s visit schedule calculated from the subject’s baseline visit date in the EDC. Kits will arrive at the site at least 15 days prior to the start of the 90-day study visit window. However, sites may still order kits and labels on demand through the kit ordering module in the event of an unscheduled visit, lost labels, etc.

For new subjects, sites must order the BL visit kit using the kit ordering module. Kits should be ordered with as much advance notice as possible to ensure that all necessary supplies will be on site for the BL visit.

## 2.6 Kit and Label Ordering on Demand

Sites will have the ability to request kits and labels on demand at any time. Refer to the sample collection schedule (Section 3.0) to verify which kits are needed for a particular visit. In the “electronic kit ordering” module, start by selecting site number and name from the list provided. This will automatically populate with the site coordinator’s contact and shipping information on file. Verify that this information is correct (and modify it if necessary). Select the kit types and/or labels needed, and then provide the quantity of kits needed, as well as the PPMI ID(s) for the subject(s) for whom the kits will be used. Click “Submit” to send your request. See Appendix F for details.

### Study Labels



## 2.7 Assessments

Indiana University will provide sites with paper copies of cognitive assessments, including the Benton Line Judgment Orientation test, the Hopkins Verbal Learning test, and the Boston Naming Test, as well as the University of Pennsylvania Smell Identification Test (UPSIT). Additional assessments can also be ordered using the kit ordering module.

## 3.0 Sample Collection Schedule

Visit	BL	V02	V04	V05	V06	V08	V10	V12	V13	V14	V15	V16	V17	V18	V19	V20
Month	0	6	12	18	24	36	48	60	72	84	96	108	120	132	144	156
Study Arm																
HC, PD																
Prodromal																
Study Visit Kit 1 (blood for RNA, plasma, buffy coat, serum, and whole blood; CSF, urine)																
Study Visit Kit 2 (blood for RNA, plasma, buffy coat, serum, and whole blood; urine)																

For approved sites, a single punch skin biopsy will be collected for subjects transitioning from PPMI 1.0 to PPMI at the first feasible post-transition visit. The single punch skin biopsy will be collected for newly enrolled PPMI subjects at BL, V06, and V10. Selected sites will complete a double punch skin biopsy at the next feasible visit for HC and idiopathic PD subjects who have agreed to participate in this ancillary protocol.

## 4.0 Equipment Required at Clinical Sites

In order to process samples consistently across all sites and ensure the highest quality sample possible, sites must have access to the following equipment:

- 4°C Refrigerated and Room Temperature Centrifuge
- -80°C Freezer
- 4°C Refrigerator

### **Important Note**

In order to ensure that the highest quality samples are collected, processed, and stored, it is essential to follow the specific collection, processing, and shipment procedures detailed in the following pages.

Please read the following instructions first before collecting and specimens. Have all your supplies and equipment out and prepared prior to specimen collection.

## 5.0 Packaging and Shipping Instructions

### 5.1 Sites Shipping to Indiana University

Please refer to Appendix C for detailed instructions regarding frozen sample shipment.

Please refer to Appendix T for detailed instructions regarding biopsy sample shipment.

### 5.2 Sites Shipping to BioRep

Please refer to Appendix D for detailed instructions regarding frozen sample shipment.

### **Important Notes**

Include a sample set for only one subject per shipping carton in order to have room for a sufficient amount of dry ice to keep samples frozen up to 24 hours unless otherwise arranged with your biorepository. Ship all frozen samples Monday through Wednesday ONLY. Be aware of holidays.

Ship biopsy samples Monday through Thursday only.

## 6.0 Sample Quality Checks and Feedback to Sites

In addition to tracking and reconciliation of samples, the condition and number of samples received is tracked by Indiana University/BioRep/Tel Aviv for each sample type received. Sites are responsible to ensure the requested amounts of each fluid are collected to the best of their ability and samples are packed well with sufficient amounts of dry ice to avoid thawing in the shipment process. Indiana University and BioRep will complete a Nonconformance Report (Appendix J) should there be any issues with a shipment and will provide this feedback to the site. Issues of concern that may impact collection, processing, or future analyses of the samples will be addressed by the PPMI Steering Committee and communicated to sites.

## **7.0 Data Queries and Reconciliation**

The appropriate information pertaining to the collection of each sample must be entered into the study EDC database on the day that samples are collected, in order to accurately capture the details pertaining to sample collection and processing. These data include information that will be used to reconcile sample collection and receipt, as well as information essential to future analyses.

Indiana University will collaborate with the Laboratory of Neuro Imaging (LONI) to reconcile information captured in the EDC database compared to samples received and accessioned at Indiana University. Any information that appears incorrect in the EDC database will be queried.

Data queries regarding samples shipped versus received at Indiana University/BioRep/Tel Aviv may result from:

- Missing samples at Indiana University/BioRep/Tel Aviv and/or corresponding data
- Incorrect samples collected and shipped to Indiana University/BioRep/Tel Aviv
- Damaged or incorrectly prepared samples
- Unlabeled samples, samples labeled with incomplete information, or mislabeled samples
- Discrepant information documented on the Sample Record Summary and Shipment Notification Form and logged in at Indiana University compared to information entered into EDC

## **8.0 Appendices**

Please see the applicable appendices for information on sample collection, kit components and ordering, nonconformance, and shipping.