



PARKINSON'S  
PROGRESSION  
MARKERS  
INITIATIVE

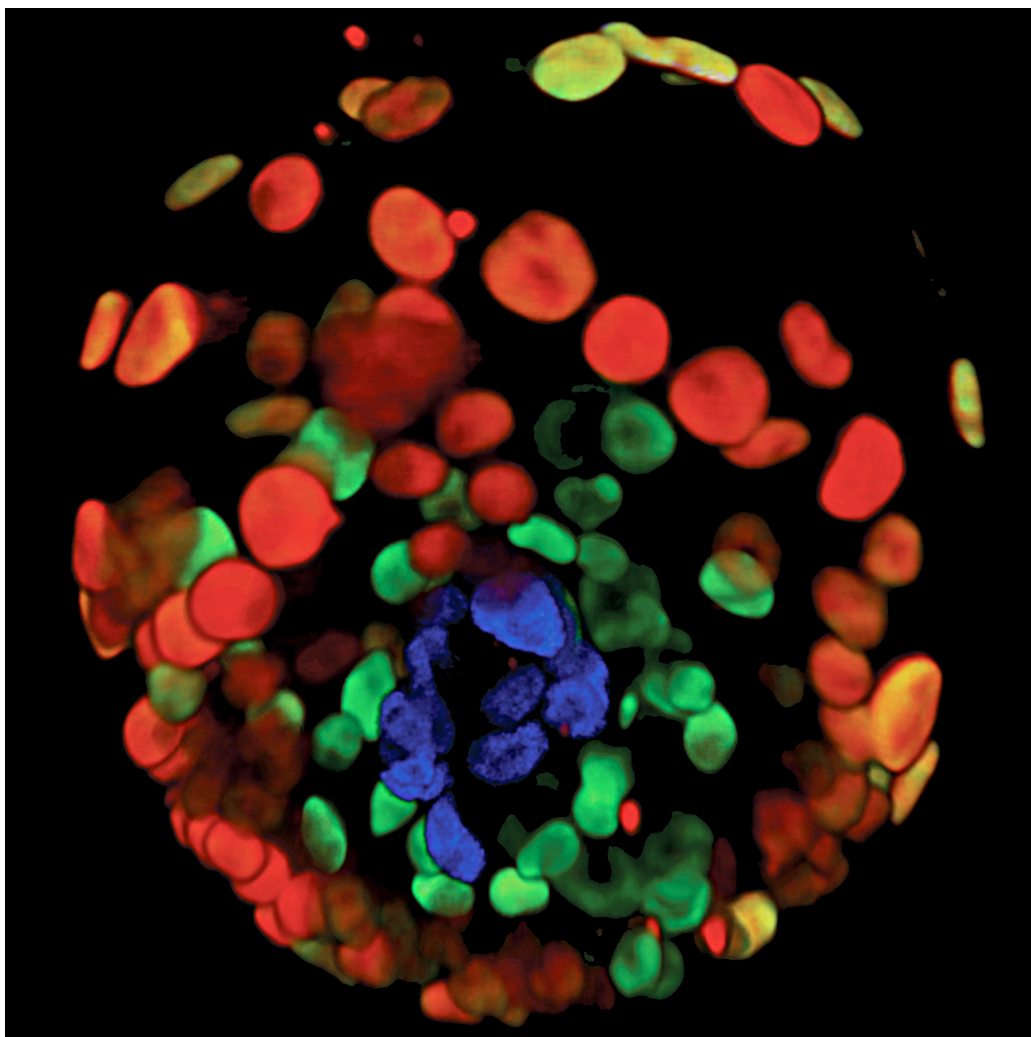
**NYSCF**

**The New York  
Stem Cell Foundation  
Research Institute**

Play a Part in Parkinson's Research

## **Skin Biopsy Collection and Transport Manual**

The New York Stem Cell Foundation



Revised September 18, 2014





## Table of Contents

<a href="#">NYSCF Contacts and Address.....</a>	<a href="#">3</a>
<b>Contacts: .....</b>	<b>3</b>
<b>Mailing Address: .....</b>	<b>3</b>
<a href="#">Equipment and Supplies .....</a>	<a href="#">4</a>
<b>Equipment Required at the Clinic Site.....</b>	<b>4</b>
<b>Specimen Collection Clinic Supplies: .....</b>	<b>4</b>
<b>Specimen Collection Laboratory Supplies: .....</b>	<b>4</b>
<b>Shipping supplies: .....</b>	Error! Bookmark not defined.
<a href="#">Biopsy Procedure .....</a>	<a href="#">5</a>
<b>Precollection: .....</b>	<b>5</b>
<b>Biopsy Collection and Processing Procedures: .....</b>	<b>5</b>
<b>Biopsy Site Care: .....</b>	<b>6</b>
<b>Suture procedure: .....</b>	<b>7</b>
<b>Storage: .....</b>	<b>7</b>
<a href="#">Packing and Shipping .....</a>	<a href="#">7</a>
<b>Packaging:.....</b>	<b>7</b>
<b>Shipping: .....</b>	<b>7</b>





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## PPMI Skin Biopsy Collection and Transport Manual

### **New York Stem Cell Foundation (NYSCF) Contacts and Address:**

#### **Contacts:**

##### **Katie Brenner**

Director, Project Management  
Phone: (212) 851-5422 Ext: 101  
Fax: (212) 851-5423  
E-Mail: KKrumholz@NYSCF.org  
*\*Lab/sample related questions*

##### **Lauren Bauer Vensand**

Associate Director, Project  
Management  
& Laboratory Operations  
Phone: 212-851-5422 Ext: 101  
Fax: (212) 851-5423  
E-mail: lvensand@nyscf.org

##### **Daniel Paull**

Senior Director, Automation Systems &  
Stem Cell Biology  
Phone: (212) 851-5422  
Fax: ((212) 851-5423  
Email: dpaul@nyscf.org

##### **Scott Noggle**

Vice President of Stem Research  
Phone: 212-851-5422 Ext: 106  
Fax: (212) 851-5423  
E-mail: snoggle@nyscf.org

##### **Stephen Chang**

Vice President of Research and  
Development  
Phone: 212-851-5422 Ext: 108  
Fax: (212) 851-5423  
E-mail: schang@nyscf.org

##### **Eliana Forero**

Associate Director, Human Subjects  
Research  
Phone: (212) 927-1801  
Fax: (480) 751-1592  
E-mail: eforero@nyscf.org  
*\*Clinic related questions*

#### **Mailing Address:**

NYSCF Laboratory:  
3960 Broadway  
Room 404  
New York, NY 10032

Revised September 18, 2014





## NYSCF Information

### Hours of Operation

NYSCF operates from 9:30am to 5pm.

### NYSCF Holiday Schedules

Please contact the NYSCF HSR Office for the most current holiday schedule.

**Samples must be shipped Monday – Wednesday only**

**Weekend/holiday delivery must be arranged in advance with NYSCF.**

\*CTCC may distribute additional shipping restrictions due to inclement weather or planned closures. Individual collection site questions should be directed to NYSCF.

## Holiday Observations

## Equipment and Supplies

### Equipment Required at the Clinic Site:

- 4°C Refrigerator (+/- 6°C) monitoring
- Storage area for shipping boxes and supplies

### Specimen Collection Supplies Required of the Clinic:

Each clinic will have the following stocked and ready for the collection of the biopsy procedure.

• Safety Glasses
• Gloves
• Disposable 3mm biopsy punch with plunger
• Disposable suture tray (includes needle, driver, forceps, scissors and gauze) and 6-0 prolene suture material
• Bandage flexible 1x3 inches
• SteriStrip Tegaderm wound closure system
• Gauze non-sterile
• Triple antibiotic ointment or Bacitracin
• Chloraprep One-Step
• 3mL Syringes
• 22 gauge needle to draw up, 30 gauge needle to inject
• Lidocaine HCl 1% with Epinephrine (1:100,000)

### Specimen Collection Laboratory Supplies to be provided by NYSCF:

To be supplied by NYSCF upon the request of the collection site.

- **Sample ID labels:** The CTCC will provide NYSCF with the appropriate PPMI IDs at the initiation of a new clinic. NYSCF will generate the labels and send them as a one-time shipment to the clinic. These will be sent in duplicates, one for the collection tube, the corresponding CRF and the reconciliation form.
- **Specimen kit:** Will be shipped upon the request of the clinic, based on their appointment schedule.





• Collection:
○ 15ml conical tubes with 10mls of collection media*
○ Parafilm
○ Biohazard bags
○ Reconciliation form
○ Kit labels
• Shipping:
○ Insulated shipping boxes
○ Gel packs
○ Pre-paid UPS shipping labels
○ Packing slip

**\*Please note: The collection media will be provided separate from the specimen collection kit as the media expires 4 weeks from the date of manufacture. The expiration date will be printed on the media tube. Please ensure your clinic has an adequate supply of media for upcoming biopsies. To order additional media, contact the NYSCF team 1 week prior to requested delivery date.**

## Biopsy Procedure

### Precollection:

Before the biopsy is collected, the volunteer will be screened and undergo an informed consent session. The doctor will explain the study, and the volunteer will have an opportunity to ask questions. Once the volunteer has read the consent, and signed the forms, the volunteer is ready for the biopsy procedure. Prior to the procedure, please be sure that the collection tube and corresponding forms have been properly labeled with the corresponding patient ID label.

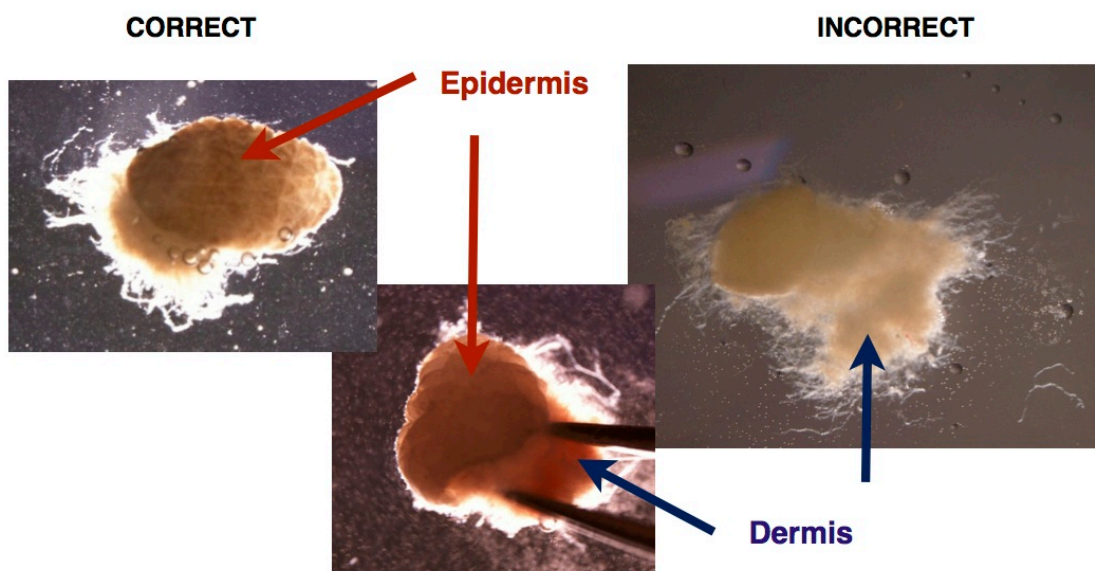
### Biopsy Collection and Processing Procedures:

1. Assure that the biopsy site has been properly sterilized with Chloraprep One Step. A punch biopsy is a clean procedure not a sterile procedure, and therefore, sterile gloves and gown are not required. Wearing safety glasses is recommended.
2. Anesthetize the area by injecting the Lidocaine solution (Lidocaine HCL 1% 1:100,000) just under the epidermis (subepidermally) using 3cc syringe just prior to the biopsy. The injection should continue until a "bleb" or small bubble forms under the skin (approximately 3mm in diameter). The injection will burn slightly (much like a bee sting) due to a pH difference between the skin and the solution. The burning will subside quickly, and the site will become numb. It is acceptable to massage the area.
3. After the Lidocaine injection, the area to be biopsied should be checked to ensure the skin is properly anesthetized. If the patient experiences neither pain nor sharp sensation, the area is ready to be biopsied. Experiencing a pressure sensation is normal but there should be no pain. If the area requires more anesthesia, another injection of Lidocaine solution is made with a new syringe.





4. Using a sterile 3mm skin punch, place the punch perpendicular to the skin and apply constant pressure while twisting the tool clockwise, in a downward motion until the blade has pierced the epidermis of the skin (there will be a "give" once the punch reached the subcutaneous fat). Once the tool has reached the lowest point, lift the tool straight up.
5. Depress the plunger to remove the specimen. The specimen should be placed directly in the conical tube and submerged in media. Using a punch with a plunger should help to ensure that the epidermis is not crushed or damaged by during the process.
6. Wipe any excess blood with a sterile 2x2 gauze to expose the site. Apply the appropriate ointment to the biopsy site, and cover with a band-aid. This can be reinforced with gauze and tape if necessary. Other closure options include using a steri-strip and tegaderm closure system. If necessary a suture may need to be placed.



#### Biopsy Site Care:

There will be some light bleeding at the biopsy site, which may continue throughout the day, and will be absorbed by the band-aid and extra gauze (if needed). The biopsy site should be kept clean. The site should not be washed for 24 hours, and should not be submerged in water (i.e. swimming, hot tubs, baths, etc) for 72 hours. The bandage should be changed daily, if it is exposed to water. The bandage can be removed once a scab, or new skin, begins to form and any bleeding





has stopped.

### **Suture procedure:**

Primary closure of a punch wound can be accomplished with one or two, single-layer, interrupted sutures. The most common closure technique is a simple, interrupted suture. Holding the needle driver in your palm, wrap the thumb and fingers around the handles, and extend the index finger down over the tip of the holder near the needle. The needle point is placed perpendicular to the skin surface about 2 mm away from the wound edge, and is driven down, and then up exiting the skin on the opposite side, again 2 mm from the wound edge and perpendicular to the surface, so the wound edges are approximated and everted. The instrument tie is fast and efficient. To begin, hold the needle holder parallel to the long axis of the wound with the free end and needle end of the suture on either side of the holder. Wrap the needle end of the suture twice around the holder, then grasp the free end of the suture with the holder and pull through, tightening the knot. At this point the needle end and free end of the suture should have switched sides relative to the beginning. The process is repeated as needed, reversing the position of the free end and needle end of the suture with each knot (tie 5 knots). Remember, "approximate, don't strangulate." Excessive tension can be recognized by blanching of the wound edges. The stitch should be removed in approximately 7 days.

### **Storage:**

Samples must be stored in media at 4°C (+/- 6°C). Samples should not be kept in media for longer than 5 days, from the time of collection to the time of processing. Please plan shipping accordingly.

Cold packs should be kept refrigerated for at least 24 hours before shipping. Frozen cold packs should never be sent with samples.

## **Packing and Shipping**

### **Packaging:**

Sample tubes should be packed in biohazard bags (double when necessary). The samples should then be placed in perishable insulated shipping boxes with cold packs.

### **Shipping:**

The Human Subjects Research Coordinator should be notified of any shipments using a completed packing slip (appendix B), which will be printed out and included in the shipping box. Shipments should be made Monday-Wednesday via overnight delivery to assure safe delivery throughout the work week.

The box should be clearly labeled with the following address:

Eliana Forero  
NYSCF  
3960 Broadway  
Room 404  
New York, NY 10032





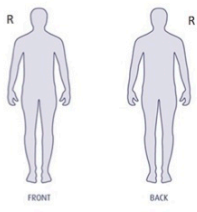


## Appendix A: Reconciliation Form

PPMI Skin Biopsy Kit Reconciliation and Shipping Notification Form					
Biopsy Kit Components					
** Upon receipt, please check that the kit has the following contents **					
	Item	Quantity		Item	Quantity
<input type="checkbox"/>	Biohazard Labels	1	<input type="checkbox"/>	Cold Packs	2
<input type="checkbox"/>	Biohazard Bag	1	<input type="checkbox"/>	Barcode Labels	10
<input type="checkbox"/>	Perishable shipping box	1	<input type="checkbox"/>	Reconciliation Form	1
<input type="checkbox"/>	MSDS (Medium 106 + Low Serum Growth Supplement): <a href="https://tools.lifetechnologies.com/content/sfs/msds/2012/M106500_MTR-NALT_EN.pdf">https://tools.lifetechnologies.com/content/sfs/msds/2012/M106500_MTR-NALT_EN.pdf</a>  <a href="https://tools.lifetechnologies.com/content/sfs/msds/2013/S00310_MTR-NALT_EN.pdf">https://tools.lifetechnologies.com/content/sfs/msds/2013/S00310_MTR-NALT_EN.pdf</a>	1	<input type="checkbox"/>	Parafilm square (1" x 1")	1
<input type="checkbox"/>	Other: _____	_____	<input type="checkbox"/>	Other: _____	_____

Please note:  
A single kit should be used for each biopsy collected. Collect and ship the biopsy per the protocol indicated in the PPMI Biopsy Collection and Transport Manual.

Check List for Clinic					
<input type="checkbox"/>	PPMI subject number:		<input type="checkbox"/>	Site number:	
<input type="checkbox"/>	Principal Investigator:		<input type="checkbox"/>	Coordinator:	
<input type="checkbox"/>	PPMI visit number		<input type="checkbox"/>	Date of biopsy:	
<input type="checkbox"/>	Expiration date on media tube		<input type="checkbox"/>	Physician:	
<input type="checkbox"/>	3mm Punch Biopsy	<input type="checkbox"/>	Other		

<p>Mark the site on the adjacent diagram where the biopsy was collected.</p> <p><i>Note: If there are adjacent anatomical structures in close proximity, please be more specific in the "Notes on collection" section. (e.g. left ear and left cheek would be hard to indicated on the diagram, so please mark the left side of the face as well as note the specific site in the notes section)</i></p>		<p>Notes on collection:</p>
--	---	-----------------------------

<input type="checkbox"/>	Sample should go directly in the media tube. The tube should be tightly closed and parafilmed and labeled with a barcode.
<input type="checkbox"/>	Place kit barcode here:
<input type="checkbox"/>	Place biohazard bag, reconciliation form, consent form into shipping envelope, seal and place into 4C refrigerator until shipping back to NYSCF
<input type="checkbox"/>	Date E-mail confirmation sent to <a href="mailto:HSR@NYSCF.org">HSR@NYSCF.org</a> : _____
<input type="checkbox"/>	UPS tracking number: _____







NYSCF Only Section				
Biopsy Kit Components				
** Please record the information below when it arrives back to NYSCF **				
To Do				
<input type="checkbox"/>	Kit Barcode: _____	<input type="checkbox"/>	Biopsy Barcode: _____	
<input type="checkbox"/>	Date Received at NYSCF: _____	<input type="checkbox"/>	Received By: _____	
<input type="checkbox"/>	Max temp recorded on card: _____			
<input type="checkbox"/>	Sealed Consent Envelope to HSR department by: _____			
<input type="checkbox"/>	Note any shipping damage/delays	<input type="checkbox"/> Delay	Notes of Delay or Damage Observed	
		<input type="checkbox"/> Damage		
<input type="checkbox"/>	Biopsy rating	Size: Quality	Length (mm): _____ <input type="checkbox"/> Fat <input type="checkbox"/> Dermis <input type="checkbox"/> Epidermis	Picture file: _____





## Appendix B: Packing Slip



### PACKING SLIP SPECIMEN SHIPMENT TO NYSCF

SHIPMENT DATE:

**SHIP TO:**

The New York Stem Cell Foundation  
3960 Broadway  
4th Floor, Suites 440/450  
New York, NY 10032  
212-851-5422

**SHIPPER CONTACT INFO:**

SHIPMENT BY	Clinic Site #	NO. OF CARTONS	CARRIER
EMAIL:		CARRIER TRACKING #	

SPECIMEN TYPE	Site Subject ID	PLACE BARCODE STICKERS BELOW	Date Collected	QTY

EMAIL CONFIRMATION TO  
HSR@nyscf.org SENT ON:

Total Units

Other Comments or Special Instructions

PACKAGE PREPARED BY

Date

If you have any questions or comments regarding this shipment, please contact  
[Eliana Forero at hsr@nyscf.org, 212-927-1801]

