Skin Biopsy Collection and Transport Manual

The New York Stem Cell Foundation
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Contacts:

**Eliana Forero**  
Human Subjects Research Coordinator  
Phone: (212) 927-1801  
Fax: (480) 751-1592  
E-mail: eforero@nyscf.org
*Clinic related questions*

**Katie Krumholz**  
Director, Project Management  
Phone: (212) 851-5422  
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

**Scott Lipnick**  
Director of Scientific Programs  
Phone: (212) 365-7432  
Fax: (212) 787-5844  
Email: slipnick@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

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

Hours of Operation
NYSCF operates from 9:30am to 5pm.

NYSCF Holiday Schedules
2014 Holiday Calendar
Tuesday 12/24/13 (half day) - Wednesday 1/1/14 Winter Break & New Year's Day
Monday 1/20/14 - Martin Luther King, Jr. Birthday
Monday 2/17/14 - President's Day
Monday 5/26/14 - Memorial Day
Friday 7/04/14 - Independence Day
Monday 9/01/14 - Labor Day

*Monday 11/17/14-Friday 1/2/14 holiday break

Thursday 11/27/14 - Thanksgiving Day
Friday 11/28/14 - Day after Thanksgiving
Wednesday 12/24/14 - Early close: 3:00 pm
Thursday 12/25/14 - Christmas Day
Friday 12/26/14 - Friday after Christmas
Wednesday 12/31/14 - Early close: 3:00 pm
Thursday 1/1/15 – New Year’s Day
Friday 1/2/15 - Friday after New Year’s Day

* For the fall/winter holiday the last sample should be collected and shipped by Friday 11/14/14. The systems will be back in operation on Monday 1/5/14, and collection can resume that week. For any questions please contact the Human Subjects Research Coordinator or Project Manager at NYSCF.

UPS Holiday Schedule
Please refer to the UPS website for the most current version of the schedule
http://www.ups.com/content/us/en/resources/ship/imp_exp/operation.html

Wednesday 01/1/2014 - New Year’s Day
Monday 5/26/2014 - Memorial Day
Friday 7/4/2014 - Independence Day
Monday 9/01/2014 - Labor Day
Thursday 11/27/14 - Thanksgiving Day *
Wednesday 12/24/14 - Christmas Eve ***
Thursday 12/25/14 - Christmas *
Friday 12/26/14 - Kwanzaa/Day after Christmas ****
Wednesday 12/31/14 - New Year’s Eve **
Thursday 1/1/15 - New Year’s Day *

*UPS holiday--UPS Express Critical® available.
**UPS holiday--Delivery and pickup of air and international packages only.
***Normal delivery of ground, air, and international shipments. Pickup of air and international shipments only.
**Delivery of air and international shipments only. Normal pickup of ground, air and international shipments.**

Samples must be shipped Monday – Wednesday only
There are no weekend deliveries.

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 biopsy collection procedure.

<table>
<thead>
<tr>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety glasses</td>
</tr>
<tr>
<td>Gloves</td>
</tr>
<tr>
<td>Disposable 3mm biopsy punch with plunger</td>
</tr>
<tr>
<td>Disposable suture tray (includes needle, driver, forceps, scissors and gauze) and 6-0 prolene suture material</td>
</tr>
<tr>
<td>Bandage flexible 1x3 inches</td>
</tr>
<tr>
<td>SteriStrip Tegaderm wound closure system</td>
</tr>
<tr>
<td>Gauze non-sterile</td>
</tr>
<tr>
<td>Triple antibiotic ointment or Bacitracin</td>
</tr>
<tr>
<td>ChloraPrep One-Step</td>
</tr>
<tr>
<td>3mL syringes</td>
</tr>
<tr>
<td>22 gauge needle to draw up, 30 gauge needle to inject</td>
</tr>
<tr>
<td>Lidocaine HCl 1% with Epinephrine (1:100,000)</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection:</td>
</tr>
<tr>
<td>o 15ml conical tubes with 10mls of collection media*</td>
</tr>
<tr>
<td>o Parafilm</td>
</tr>
<tr>
<td>o Biohazard bags</td>
</tr>
<tr>
<td>o Reconciliation form</td>
</tr>
<tr>
<td>o Kit labels</td>
</tr>
<tr>
<td>Shipping:</td>
</tr>
<tr>
<td>o Insulated shipping boxes</td>
</tr>
</tbody>
</table>
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 Lidocane 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 Lidocane 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 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

**Biozzy Kit Components**  
**Upon receipt, please check that the kit has the following contents**

<table>
<thead>
<tr>
<th>Item</th>
<th>Quantity</th>
<th>Item</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biohazard Labels</td>
<td>1</td>
<td>Cold Packs</td>
<td>2</td>
</tr>
<tr>
<td>Biohazard Bag</td>
<td>1</td>
<td>Barcode Labels</td>
<td>10</td>
</tr>
<tr>
<td>Perishable shipping box</td>
<td>1</td>
<td>Reconciliation Form</td>
<td>1</td>
</tr>
</tbody>
</table>
| MSDS (Medium 106 + Low Serum Growth Supplement):  
https://tools.lifetecnologies.com/content/sfsa/msds/2012/M106500_MTR-NAL7_EN.pdf  
https://tools.lifetecnologies.com/content/sfsa/msds/2013/300310_MTR-NAL7_EN.pdf | 1 | Parafilm square (1” x 1”) | 1 |

**Other:**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Other</th>
</tr>
</thead>
</table>

**Check List for Clinic**

- [ ] PPMI subject number:  
- [ ] Principal Investigator:  
- [ ] PPMI visit number:  
- [ ] Expiration date on media tube:  
- [ ] 3mm Punch Biopsy  
- [ ] Other

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)

- [ ] Sample should go directly in the media tube. The tube should be tightly closed and parafilmed and labeled with a barcode.

- [ ] Place kit barcode here:  
- [ ] Place biohazard bag, reconciliation form, consent form into shipping envelope, seal and place into 4C refrigerator until shipping back to NYSCF  
- [ ] Date E-mail confirmation sent to HSRI@NYSCF.org: ___________________________  
- [ ] UPS tracking number: ___________________________

NYSCF Reconciliation Form Version 9/18/14

Revised September 18, 2014
<table>
<thead>
<tr>
<th>NYSCF Only Section</th>
<th></th>
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<tbody>
<tr>
<td><strong>Biopsy Kit Components</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Please record the information below when it arrives back to NYSCF</strong></td>
<td></td>
</tr>
<tr>
<td><strong>To Do</strong></td>
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</tr>
<tr>
<td>□ Kit Barcode: ___</td>
<td>□ Biopsy Barcode: ___</td>
</tr>
<tr>
<td>□ Date Received at NYSCF: ___</td>
<td>□ Received By: ___</td>
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<tr>
<td>□ Max temp recorded on card: ___</td>
<td></td>
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<tr>
<td>□ Sealed Consent Envelope to HSR department by: ___</td>
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<tr>
<td>□ Note any shipping delays/damages</td>
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<tr>
<td>□ Delay</td>
<td>□ Damage</td>
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<tr>
<td>Notes of delay or damage observed</td>
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<tr>
<td>□ Biopsy rating</td>
<td></td>
</tr>
<tr>
<td>Size: ___</td>
<td>Length (mm): ___</td>
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<tr>
<td>Quality</td>
<td>□ Fat</td>
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# Appendix B: Packing Slip

**PACKING SLIP**  
**SPECIMENT SHIPMENT TO NYSCF**

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

<table>
<thead>
<tr>
<th>SHIPMENT BY</th>
<th>Clinic Site #</th>
<th>NO. OF CARTONS</th>
<th>CARRIER</th>
<th>EMAIL:</th>
<th>CARRIER TRACKING #</th>
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**SPECIMEN TYPE** | **Site Subject ID** | **PLACE BARCODE STICKERS BELOW** | **Date Collected** | **QTY** |
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**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]

Revised September 18, 2014