Attachment 2d

PATH Study Data Collection Instruments: Biospecimen Collection Forms

July 23, 2012

Blood Data Collection Form

Respondent ID (Text Readable Barcode) **DCN** OMB Control Number: 0925-XXXX
Date Printed Expiration Date:

PATH Study
Blood Data Collection Form

Part A: Administrative	**Part G: Blood Collection Status**
1. Staff ID: *Preprinted* **2. Today's Date:** |__|__|/|__|__|/|__|__|__|__| M M D D Y Y Y Y **1. Blood Collection:** ☐ Agreed ☐ Not Agreed (Go to Part G)	**1. Collection Status (Mark one):** ☐ Collected (End) ☐ Attempted, Not Collected ☐ Not Collected **2. Reason not collected (Mark one main reason):** ☐ Respondent refused ☐ Safety exclusion ☐ Respondent ill/emergency ☐ No time ☐ Cognitive disability ☐ Language issue ☐ Defective/missing collection supplies ☐ Physical limitations (Specify): _____ ☐ Other--specify: _____

Part B: Blood Suitability Questions	
1. Have you had cancer chemotherapy within the past 2 weeks? ☐ Yes ☐ No ☐ Refused ☐ Don't Know	**3. What problems have you had with a blood draw in the past? (Mark all that apply.)** ☐ Fainting ☐ Light-headedness ☐ Hematoma ☐ Bruising ☐ Other- Specify _____
2. Have you had any problems with a blood draw in the past? ☐ Yes ☐ Refused (Go to Part C) ☐ No (Go to Part C) ☐ Don't Know (Go To Part C)	

Part C: Blood Kit ID	**Part D: Blood Tube Status**			
1. Blood Kit ID: ***(Place Label Here)***	Blue Top Tube (BT01)	☐ ***Full draw***	☐ ***Short draw***	☐ ***No draw***
	Red Top Tube #1 (RD01)	☐ ***Full draw***	☐ ***Short draw***	☐ ***No draw***
	Red Top Tube #2 (RD02)	☐ ***Full draw***	☐ ***Short draw***	☐ ***No draw***
	Lavender Tube #1 (LV01)	☐ ***Full draw***	☐ ***Short draw***	☐ ***No draw***
	Lavender Tube #2 (LV02)	☐ ***Full draw***	☐ ***Short draw***	☐ ***No draw***
	PAXgene Tube (PX01)	☐ ***Full draw***	☐ ***Short draw***	☐ ***No draw***

Part E: Blood Collection Results

1. Collection Time:

|__|__| : |__|__| ☐ a.m. ☐ p.m.
H H M M

2. Time placed in shipping container:

|__|__| : |__|__| ☐ a.m. ☐ p.m.
H H M M

3. Problems with the blood draw? (Mark all that apply.)

☐ No problems
☐ Fainting
☐ Light-headedness
☐ Hematoma
☐ Bruising
☐ Other- Specify _____

Part F: Comments

_____

_____

➢ **GO TO TOP OF FORM AND COMPLETE PART G BLOOD COLLECTION STATUS**

Buccal Cell Data Collection Form

Respondent ID **DCN** OMB Control Number: 0925-XXXX
Date Printed Expiration Date:

PATH Study
Buccal Cell Data Collection Form
Interviewer Administered

Part A: Administrative

1. **Staff ID:** *Preprinted*

2. **Today's Date:**
|__|__|/|__|__|/|__|__|__|__|
M M D D Y Y Y Y

3. **Buccal Cell Collection:**
- ☐ Agreed
- ☐ Not agreed (Go to Part E)

4. **Buccal Cell Kit ID:**
(Go to Part B)
(Place Label Here)

Part E: Buccal Cell Collection Status

1. **Collection Status (Mark one):**
- ☐ Collected (End)
- ☐ Attempted, not collected
- ☐ Not collected

2. **Reason Not Collected (Mark one main reason):**
- ☐ Respondent refused
- ☐ Respondent ill/emergency
- ☐ Cognitive disability
- ☐ Sores/Ulcers
- ☐ Dry mouth
- ☐ Infection
- ☐ Physical limitations (Specify): _____
- ☐ Other--specify: _____
- ☐ No time
- ☐ Language issue
- ☐ Defective/missing collection supplies
- ☐ Cuts/Bleeding
- ☐ Cancer

Part B: Buccal Cell Collection Questions

1. **Do you have any special conditions in your mouth (e.g. sores, signs of infection, bleeding, etc.)?**
☐ Yes ☐ No **(Go to Q3)** ☐ Don't know **(Go to Q3)** ☐ Refused **(Go to Q3)**

2. **What mouth condition(s) do you have? (Mark all that apply)**
☐ Sores/Ulcers ☐ Cuts/Bleeding ☐ Dry mouth
☐ Infection ☐ Cancer
☐ Other: _____

3. **When was the last time you had anything to eat or drink other than water?**
☐ Don't know ☐ Refused
Date: |__|__| / |__|__| / |__|__|__|__|
M M D D Y Y Y Y
Time: |__|__| : |__|__| ☐ a.m. ☐ p.m.
H H M M

4. **When was the last time you brushed your teeth?**
☐ Don't know ☐ Refused
Date: |__|__| / |__|__| / |__|__|__|__|
M M D D Y Y Y Y
Time: |__|__| : |__|__| ☐ a.m. ☐ p.m.
H H M M

5. **Have you had cancer chemotherapy within the past 2 weeks?**
☐ Yes ☐ No ☐ Don't know ☐ Refused

Part C: Buccal Cell Collection Results

1. **Collection Time:** |__|__| : |__|__| ☐ **a.m.** ☐ **p.m.**
   H H M M

2. **Number of Scrapers Used:** _____

3. **Order of Scrapers for Collection:** ☐ Right, Left, Right, Left, Both ☐ Other--specify:_____

4. **Time placed in shipping container:** |__|__| : |__|__| ☐ a.m. ☐ p.m.
   H H M M

Part D: Comments _____

_____

➢ **GO TO TOP OF FORM AND COMPLETE PART E BUCCAL CELL COLLECTION STATUS**

Urine Data Collection Form

Respondent ID **DCN** OMB Control Number: 0925-XXXX
Date Printed Expiration Date:

PATH Study
Urine Data Collection Form
Interviewer/Phlebotomist Administered

Part A: Administrative

5. Staff ID: *Preprinted*

6. Today's Date:

|__|__|/|__|__|/|__|__|__|__|
M M D D Y Y Y Y

7. Urine Collection:

☐ Agreed
☐ Not agreed (Go to Part E)

8. Urine Kit ID: (Go to Part B)

(Place Label Here)

Part E: Urine Collection Status

1. Collection Status (Mark one):

☐ Collected (End)
☐ Attempted, not collected
☐ Not collected

2. Reason Not Collected (Mark one main reason):

☐ Respondent refused ☐ No time
☐ Respondent ill/emergency ☐ Language issue
☐ Cognitive disability
☐ Defective/missing collection supplies
☐ Physical limitations (Specify): _____
☐ Other--specify: _____

Part B: Urine Collection Questions

1. When was the last time you urinated?
☐ Don't know ☐ Refused

Date: |__|__| / |__|__| / |__|__|__|__|
M M D D Y Y Y Y

Time: |__|__| : |__|__| ☐ a.m. ☐ p.m.
H H M M

2. When was the last time you had anything to eat or drink other than water?
☐ Don't know ☐ Refused

Date: |__|__| / |__|__| / |__|__|__|__|
M M D D Y Y Y Y

Time: |__|__| : |__|__| ☐ a.m. ☐ p.m.
H H M M

3. Have you had cancer chemotherapy within the past 2 weeks?

☐ Yes ☐ No ☐ Don't know ☐ Refused

Part C: Urine Collection Results

1. Specimen ID: *(Place Label Here)*

2. Collection time: |__|__| (H H) : |__|__| (M M) ☐ a.m. ☐ p.m.

3. Time placed in shipping container: |__|__| (H H) : |__|__| (M M) ☐ a.m. ☐ p.m.

Part D: Comments _____

_____

➢ **GO TO TOP OF FORM AND COMPLETE PART E URINE COLLECTION STATUS**