

Attachment 2d

**PATH Study Data Collection Instruments:
Biospecimen Collection Forms**

July 23, 2012

Blood Data Collection Form

Respondent ID (Text Readable Barcode)
Date Printed

DCN

OMB Control Number: 0925-XXXX
Expiration Date:

PATH Study Blood Data Collection Form

Part A: Administrative		Part G: Blood Collection Status	
<p>1. Staff ID: <i>Preprinted</i></p> <p>2. Today's Date:</p> <p style="text-align: center;"> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>M M D D Y Y Y Y</small> </p> <p>1. Blood Collection:</p> <p><input type="checkbox"/> Agreed</p> <p><input type="checkbox"/> Not Agreed (Go to Part G)</p>		<p>1. Collection Status (Mark one):</p> <p><input type="checkbox"/> Collected (End)</p> <p><input type="checkbox"/> Attempted, Not Collected</p> <p><input type="checkbox"/> Not Collected</p> <p>2. Reason not collected (Mark one main reason):</p> <p><input type="checkbox"/> Respondent refused <input type="checkbox"/> Safety exclusion</p> <p><input type="checkbox"/> Respondent ill/emergency <input type="checkbox"/> No time</p> <p><input type="checkbox"/> Cognitive disability <input type="checkbox"/> Language issue</p> <p><input type="checkbox"/> Defective/missing collection supplies</p> <p><input type="checkbox"/> Physical limitations (Specify): _____</p> <p><input type="checkbox"/> Other--specify: _____</p>	
Part B: Blood Suitability Questions			
<p>1. Have you had cancer chemotherapy within the past 2 weeks?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Refused <input type="checkbox"/> Don't Know</p>		<p>3. What problems have you had with a blood draw in the past? (Mark all that apply.)</p> <p><input type="checkbox"/> Fainting <input type="checkbox"/> Light-headedness</p> <p><input type="checkbox"/> Hematoma <input type="checkbox"/> Bruising</p> <p><input type="checkbox"/> Other- Specify _____</p>	
<p>2. Have you had any problems with a blood draw in the past?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> Refused (Go to Part C)</p> <p><input type="checkbox"/> No (Go to Part C) <input type="checkbox"/> Don't Know (Go To Part C)</p>			
Part C: Blood Kit ID		Part D: Blood Tube Status	
<p>1. Blood Kit ID:</p> <p style="text-align: center;"><i>(Place Label Here)</i></p>		Blue Top Tube (BT01)	<input type="checkbox"/> <i>Full draw</i> <input type="checkbox"/> <i>Short draw</i> <input type="checkbox"/> <i>No draw</i>
		Red Top Tube #1 (RD01)	<input type="checkbox"/> <i>Full draw</i> <input type="checkbox"/> <i>Short draw</i> <input type="checkbox"/> <i>No draw</i>
		Red Top Tube #2 (RD02)	<input type="checkbox"/> <i>Full draw</i> <input type="checkbox"/> <i>Short draw</i> <input type="checkbox"/> <i>No draw</i>
		Lavender Tube #1 (LV01)	<input type="checkbox"/> <i>Full draw</i> <input type="checkbox"/> <i>Short draw</i> <input type="checkbox"/> <i>No draw</i>
		Lavender Tube #2 (LV02)	<input type="checkbox"/> <i>Full draw</i> <input type="checkbox"/> <i>Short draw</i> <input type="checkbox"/> <i>No draw</i>
		PAXgene Tube (PX01)	<input type="checkbox"/> <i>Full draw</i> <input type="checkbox"/> <i>Short draw</i> <input type="checkbox"/> <i>No draw</i>

Part E: Blood Collection Results	
<p>1. Collection Time:</p> <p> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <small>H H M M</small> </p> <p>2. Time placed in shipping container:</p> <p> <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <small>H H M M</small> </p>	<p>3. Problems with the blood draw? (Mark all that apply.)</p> <p> <input type="checkbox"/> No problems <input type="checkbox"/> Fainting <input type="checkbox"/> Light-headedness <input type="checkbox"/> Hematoma <input type="checkbox"/> Bruising <input type="checkbox"/> Other- Specify _____ </p>
Part F: Comments	
<hr/> <hr/>	

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

Public reporting burden for this collection of information is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

Buccal Cell Data Collection Form

Respondent ID
Date Printed

DCN

OMB Control Number: 0925-XXXX
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):

- | | |
|--|--|
| <input type="checkbox"/> Respondent refused | <input type="checkbox"/> No time |
| <input type="checkbox"/> Respondent ill/emergency | <input type="checkbox"/> Language issue |
| <input type="checkbox"/> Cognitive disability | <input type="checkbox"/> Defective/missing collection supplies |
| <input type="checkbox"/> Sores/Ulcers | <input type="checkbox"/> Cuts/Bleeding |
| <input type="checkbox"/> Dry mouth | <input type="checkbox"/> Cancer |
| <input type="checkbox"/> Infection | |
| <input type="checkbox"/> Physical limitations (Specify): _____ | |
| <input type="checkbox"/> Other--specify: _____ | |

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**

Public reporting burden for this collection of information is estimated to average 3 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-XXXX). Do not return the completed form to this address.

Urine Data Collection Form

Respondent ID
Date Printed

DCN

OMB Control Number: 0925-XXXX
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: |__|__| : |__|__| a.m. p.m.
 H H M M

- 3. 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 URINE COLLECTION STATUS**

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