

Attachment 17

Field Data Collection Materials

July 23, 2012

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RS1 – Language Identification Card

[PATH LOGO]

Population Assessment of Tobacco and Health (PATH) Study Language Identification Card

[IF THE INTERVIEWER IS UNABLE TO UNDERSTAND THE LANGUAGE OF THE PERSON AT THE DOORSTEP, THE INTERVIEWER WILL USE THIS CARD TO IDENTIFY THE LANGUAGE SPOKEN]

(This card will be translated into Spanish, Mandarin, Cantonese, Korean, and Vietnamese)

“Please tell us what language is used in this household.”

RS2 – Introduction Card for When Interviewer Unable to Understand Non-English Study Language

[PATH LOGO]

Population Assessment of Tobacco and Health (PATH) Study Introduction Card

[IF THE INTERVIEWER IS UNABLE TO UNDERSTAND THE LANGUAGE OF THE PERSON AT THE DOORSTEP, THE INTERVIEWER WILL USE THIS CARD AFTER USING THE LANGUAGE IDENTIFICATION CARD TO IDENTIFY THE NON-ENGLISH STUDY LANGUAGE SPOKEN]

(This card will be translated into Spanish, Mandarin, Cantonese, Korean, and Vietnamese)

Hello. I work for a company called Westat. We are conducting a very important research study called the Population Assessment of Tobacco and Health (PATH) study. This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Is an adult who can speak English available to talk with me?

[IF AN ADULT WHO SPEAKS ENGLISH IS AVAILABLE, THE INTERVIEWER WILL PROCEED WITH INTRODUCING THE STUDY AND CONDUCTING THE SCREENER]

[IF NO ADULT WHO SPEAKS ENGLISH IS AVAILABLE, THE INTERVIEWER WILL SHOW THE HOUSEHOLD MEMBER THE FOLLOWING TEXT, WHICH INDICATES SOMEONE WHO SPEAKS HIS/HER LANGUAGE WILL CONTACT HIM/HER]

Someone from my office who speaks your language will contact you later. Can you please give me your phone number?

We appreciate your help with this study.

RS3 – Sorry I Missed You (SIMY) Card

[PATH LOGO]

Sorry I Missed You

Hello _____:

I visited today to talk with you about the Population Assessment of Tobacco and Health (PATH) study. This study will look at tobacco use and how it affects the health of people in the United States. It will include both people who use tobacco and those who don't. This study is being conducted by Westat for the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). I'm sorry that I didn't find you at home. In the next few days, I'll try to contact you again.

If you want more information about this study or to schedule an appointment at a convenient time, please call us toll-free at 1-800-xxx-xxxx between 9:00 am and 5:30 pm Eastern Time. You may also visit the PATH study website at [PATH URL] (if you have a smartphone, you can scan the QR code below to visit the website).


Thank you for your cooperation.

Sincerely,

[INTERVIEWER NAME AND DATE, CLEARLY PRINTED]

[PATH QR Code]

RS4 – Interviewer ID Badge

	PATH Population Assessment of Tobacco and Health
Interviewer Photo	Jane P. Doe <i>Jane P Doe</i> Expires: 9-30-2016
<u>Issued by: Westat Project Director, David Maklan, Ph.D.</u>	
1-800-222-2222 www.pathstudyinfo.org	

RS5 – Interviewer Authorization Letter

To Whom It May Concern:

The bearer of this letter, [INTERVIEWER NAME], is a professionally trained researcher who works for Westat, an independent research firm. Westat is conducting the Population Assessment of Tobacco and Health (PATH) study. This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). The study will look at tobacco use and how it affects the health of people in the United States. What we learn will help improve the health of millions of Americans.

About 59,000 individuals will be asked to participate in this study. The study will include people who use tobacco and those who don't.

The researcher named in this letter is doing the PATH study interviews. He or she carries a Westat identification badge. The researcher needs to speak to someone at the selected address and other addresses in the area.

If you have any questions about the survey or this researcher's role, call Westat toll-free at 1-800-xxx-xxxx between 9:00 am and 5:30 pm Eastern Time. You can also visit the PATH study website at [PATH URL] (if you have a smartphone, you can scan the QR code below to visit the website).

Thank you in advance for your cooperation.

Sincerely,

Kevin P. Conway, Ph.D.
PATH Study, NIH Project Officer

[PATH QR Code]

RS6 – Introduction and Oral Consent Script

Phase 1 Screener Script

“Hello, my name is [INTERVIEWER]. I’m working on an important research study for the National Institutes of Health, in partnership with the Food and Drug Administration. This study is being conducted by Westat, an independent research firm. Here is my identification badge.”

[ASK TO SPEAK TO HOUSEHOLD MEMBER AGE 18 OR OLDER IF AGE IS NOT OBVIOUS]

“May I speak to an adult who lives here?”

[*WHEN SPEAKING WITH ADULT*, RE-INTRODUCE YOURSELF AND SHOW ID BADGE. CONFIRM THE ADULT IS A RESIDENT AT THE ADDRESS AND CONFIRM YOU ARE AT THE CORRECT ADDRESS ACCORDING TO THE ADDRESS IN YOUR COMPUTER]

[*IF NO ADULT IS AVAILABLE*, OBTAIN A PHONE NUMBER AND INDICATE THAT YOU WILL CALL TO MAKE AN APPOINTMENT; ASK ABOUT A GOOD TIME TO CALL BACK]

“Just to confirm, is this [STREET ADDRESS]?”

[IF YOU ARE NOT AT THE CORRECT ADDRESS, THANK THE PERSON AND LEAVE]

[IF YOU ARE AT CORRECT ADDRESS, PROCEED TO NEXT STEPS]

[HAVE THE STUDY INFORMATION VISIBLE]

“We’re conducting a nationwide study called the Population Assessment of Tobacco and Health study for the National Institutes of Health, in partnership with the Food and Drug Administration. Recently your household received information about the study. Do you remember receiving the information in the mail?”

[IF YES] **“Have you had a chance to look over the information?”**

[IF YES] **“Wonderful! Then you know this is a study to get information on tobacco and health. Do you have any questions that I can answer for you right now?”**

[ANSWER RESPONDENT’S QUESTIONS]

[IF RESPONDENT DID NOT RECEIVE THE INFORMATION OR DOES NOT REMEMBER RECEIVING INFORMATION ABOUT THE STUDY:]

- GIVE A BRIEF OVERVIEW OF THE STUDY
- SHOW INDIVIDUAL A COPY OF THE ADVANCE LETTERS
- GIVE THE RESPONDENT THE BROCHURE
- READ/REVIEW THE LETTERS WITH THE RESPONDENT
- BE SURE TO VERIFY INCORRECT OR MISSING ADDRESS INFORMATION DURING THE PHASE 1 SCREENER

[AFTER READING/REVIEWING THE LETTERS] **“Do you have any questions at this time?”**

[ANSWER QUESTIONS FROM THE RESPONDENT]

[PROCEED WITH THE SCREENER ACTIVITIES: GAINING COOPERATION, ADDRESS VERIFICATION, AND ORAL CONSENT]

“I have a few questions that will tell us whether anyone living here can take part in our study. These questions take about 15 to 20 minutes and are completely voluntary. Is it OK if I come inside?”

Your answers will be kept private. If you don’t want to answer a question, please let me know, and we can move on to the next question. At the end of this short interview, I’ll give you \$10 as a thank you for your time.

For quality control, I’d like to audio record this interview.”

[DID RESPONDENT OBJECT OR NOT OBJECT TO AUDIO RECORDING?]

- RESPONDENT OBJECTS TO RECORDING
- RESPONDENT DOES NOT OBJECT TO RECORDING

[IF RESPONDENT DOES NOT OBJECT TO RECORDING]

“Today is [DATE]. Now that the recorder is running, is it OK with you if we record this interview?”

- YES, IT’S OK TO RECORD
- NO, IT’S NOT OK TO RECORD

[ADMINISTER THE SCREENER #1]

[IF PHASE 1 SCREENER RESPONDENT IS NOT SELECTED FOR PHASE 2 SCREENER]

“I’d like to give you \$10 to thank you for your time today.”

“Please sign this form that says you received the \$10 payment and please note here” [POINT TO THE BOX THAT YOU WILL CHECK FOR THE INCENTIVE RESPONDENT RECEIVED].

“Thank you.”

[DID THE RESPONDENT ACCEPT OR DECLINE THE INCENTIVE?]

- ACCEPT
- DECLINE

Phase 2 Screener Script:

[IF PHASE 2 SCREENER RESPONDENT IS DIFFERENT FROM PHASE 1 SCREENER RESPONDENT, ASK TO SPEAK TO THAT RESPONDENT]

“Is [RESPONDENT’S NAME] available?”

[IF YES]

- REPEAT INTRODUCTORY STATEMENTS FROM SCREENER 1
- VERIFY RESPONDENT HAS KNOWLEDGE OF STUDY
- ANSWER ANY RESPONDENT QUESTIONS
- PROCEED DIRECTLY TO THE CONSENT PROCESS
 - REVIEW CONSENT DOCUMENTS
 - ANSWER ANY QUESTIONS
 - NOTE CONSENT IN COMPUTER
 - HAVE RESPONDENT SIGN CONSENT FORMS
 - REMEMBER TO GIVE RESPONDENT ORIGINAL COPY
 - RETAIN COPY FOR HOME OFFICE
- PROCEED TO HAVE THE RESPONDENT COMPLETE THE ACASI TUTORIAL AND ANSWER THE PHASE 2 SCREENER QUESTIONS USING THE ACASI PROGRAM

[IF SELECTED RESPONDENT IS NOT AVAILABLE, ASK ABOUT A GOOD TIME TO COME BACK]

[IF RESPONDENT IS THE SAME AS RESPONDENT FOR SCREENER 1:]

- PROCEED DIRECTLY TO THE CONSENT PROCESS
 - REVIEW CONSENT DOCUMENTS
 - ANSWER ANY QUESTIONS
 - NOTE CONSENT IN COMPUTER
 - HAVE RESPONDENT SIGN CONSENT FORMS
 - REMEMBER TO GIVE RESPONDENT ORIGINAL COPY
 - RETAIN COPY FOR HOME OFFICE
- PROCEED TO HAVE THE RESPONDENT COMPLETE THE ACASI TUTORIAL AND ANSWER THE PHASE 2 SCREENER QUESTIONS USING THE ACASI PROGRAM

[SET YOUR COMPUTER FOR THE RESPONDENT TO ANSWER THE QUESTIONS]

[IF NOT ELIGIBLE BASED ON PHASE 2 SCREENER]

“These are all the questions I have for you. Based on your answers, you aren’t eligible to join our study. Thank you for taking the time to answer the questions.”

“I’d like to give you \$60 to thank you for your time today.”

“All of the money you receive today will be available on this debit card [SHOW DEBIT CARD] in about 24 hours.”

“Please sign this form that says you received your debit card and please note here [POINT TO THE BOXES THAT YOU WILL CHECK FOR THE INCENTIVES RESPONDENT WILL RECEIVE] the amount of money you can expect to be available on your card as we discussed.”

“Thank you again for your time.”

[DID THE RESPONDENT ACCEPT OR DECLINE THE INCENTIVE?]

ACCEPT

DECLINE

[IF ELIGIBLE BASED ON PHASE 2 SCREENER, RESPONDENT WILL AUTOMATICALLY CONTINUE INTO THE MAIN INTERVIEW]

“Thank you for completing the interview.” The next step is to collect samples. First, I would like to go over the collection process with you and answer any questions you may have.”

[WHEN THE RESPONDENT HAS COMPLETED THE MAIN INTERVIEW:]

- REVIEW CONSENT FOR BIOSPECIMEN COLLECTION
- ANSWER QUESTIONS
- REVIEW BIOSPECIMEN COLLECTION PROCESS
- PROCEED TO COLLECT BUCCAL CELL SPECIMEN AND URINE SPECIMEN (IF RESPONDENT HAS NOT CONSENTED TO BLOOD COLLECTION OR DID NOT PASS ON BLOOD SUITABILITY)

[IF PROVIDED SPECIMENS] “Thank you for providing these samples. We appreciate your participation in this very important study. I’d like to give you \$XX as a thank you for participating”

“All of the money you receive today will be available on this debit card [SHOW DEBIT CARD] in about 24 hours. The money for the blood collection will be available about 24 hours after the visit from the person who’ll collect your blood sample.”

“Please sign this form that says you received your debit card and please note here [POINT TO THE BOXES THAT YOU WILL CHECK FOR THE INCENTIVES RESPONDENT WILL RECEIVE] the amount of money you can expect to be available on your card as we discussed.”

[DID THE RESPONDENT ACCEPT OR DECLINE THE INCENTIVE?]

ACCEPT

DECLINE

[IF RESPONDENT AGREED TO BLOOD SAMPLE COLLECTION]

“The next step in this process is the blood sample collection.”

[IF RESPONDENT DID NOT CONSENT, DO NOT ADDRESS THIS. NO REFUSAL CONVERSION METHODS WILL APPLY]

“Here is a brochure about the blood collection process. A phlebotomist – that’s a blood collection expert – from a nationally recognized company, Hooper Holmes, will visit your home to collect your blood and urine samples. After you finish that process, as a thank you, you’ll receive \$30 for the blood sample and \$10 for the urine sample.”

“I’d like to call our scheduler now to find a good time for you to have the Hooper Holmes phlebotomist visit your home.”

[CALL SCHEDULER ON YOUR CELL PHONE AND FIND THE BEST TIME FOR THE RESPONDENT TO BE VISITED]

“OK. We have you scheduled for a visit from the Hooper Holmes phlebotomist on **MMDDYY** at **HH:MM**. I’ll write this information on an appointment card for you. A few days before your appointment, the phlebotomist will call you to confirm the appointment.”

“Do you have any other questions at this time?”

“Thank you again for your time. If you have questions, please contact my supervisor **[SUPERVISOR NAME]** at **[PHONE NUMBER]**.”

RS7a – Refusal Conversion Letter – Too Busy (Refusal to Phase 1 Screener)

<Date>

< Name>

<Address>

<Address>

Dear ([Name, if available]),

Recently, someone in your household spoke with one of our interviewers about the Population Assessment of Tobacco and Health (PATH) study. This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). I understand how busy people are these days. However, your household's participation in this study is very important. We are asking for your help so that your household will take part in the study, whether or not you use tobacco. We'd like to interview someone in your household for 15 to 20 minutes. As a thank you, we will give that person \$10. If someone from your household is selected for a longer interview, we will give that person up to \$110 as a thank you for participating.

I realize that your time is valuable. However, your participation is very important to the success of the study. Researchers and policymakers will use the results of the study to improve our Nation's health. We chose your household to represent many others like it. The interviews and samples we collect will be much more complete and useful if your household and many others participate. By taking part, you'll be performing an important public service. I've enclosed a study brochure to help answer your questions.

An interviewer will come to your home soon. If you have any questions, please call our toll-free number, 1-800-xxx-xxxx, between 9:00 am and 5:30 pm Eastern Time. You can also visit our website at [PATH URL] (if you have a smartphone, you can scan the QR code below to visit the website).

Thank you in advance for your help.

Sincerely,

Scott Crosse, Ph.D.
PATH Study, Westat Director of Survey Operations

[PATH QR Code]

RS7b – Refusal Conversion Letter – Too Busy (Refusal to Main Interview)

<Date>

< Name>

<Address>

<Address>

Dear [Name, if available],

Someone in your household recently spoke with one of our interviewers about the Population Assessment of Tobacco and Health (PATH) study. This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). I understand how busy people are these days. However, your participation in the study is very important, whether you use tobacco or not. The interview should take about 75 minutes. It can be done at a time that is convenient for you. As a thank you for doing the interview, we'll give you \$60.

You were chosen to represent thousands of other individuals like yourself. Having every type of person in our Nation take part in the study is very valuable. It'll provide a better understanding of the use of tobacco and its effects on health in the United States. By taking part, you'll be performing an important public service. I've enclosed a study brochure to help answer your questions.

One of our study interviewers will contact you soon. I hope that we can schedule a good time to complete your interview. If you have any questions, please call our toll-free number, 1-800-xxx-xxxx, between 9:00 am and 5:30 pm Eastern Time. You can also visit our website at [PATH URL] (if you have a smartphone, you can scan the QR code below to visit the website).

We need and would greatly appreciate your help.

Sincerely,

Scott Crosse, Ph.D.
PATH Study, Westat Director of Survey Operations

[PATH QR Code]

RS7c – Refusal Conversion Letters – Worried About Confidentiality

<Date>

< Name>

<Address>

<Address>

Dear (Respondent Name),

Recently you or someone in your household spoke with one of our interviewers about the Population Assessment of Tobacco and Health (PATH) study. This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). Our interviewer realized that you had privacy concerns.

We appreciate your concerns. We'd like to take this opportunity to talk about them. The study is totally committed to protecting your privacy. Here are some steps we've taken.

- You'll be assigned a unique study number. Your answers will be associated with that number. They won't be directly linked to any personal identifying information, such as your name. For example, if I were a participant, none of the information I gave would have my name on it. Instead, it would have a number, such as 0021.
- Your answers will be combined with answers given by thousands of others who take part in the study.
- All researchers must sign a pledge to protect your confidentiality. We take this pledge seriously. Any researcher who violates your privacy will lose his or her job. We might also take legal action against that person.
- The study has received a Certificate of Confidentiality from the U.S. Department of Health and Human Services. With this Certificate, authorities can't force us to share your information.
- Participating in the study is completely voluntary. You may refuse to answer any question you don't feel comfortable answering. You are free to leave the study at any time.

One of our study interviewers will contact you soon. I hope that we can schedule a good time to complete your interview. If you have any questions, please call our toll-free number, 1-800-xxx-xxxx, between 9:00 am and 5:30 pm Eastern Time. You can also visit our website at [PATH URL] (if you have a smartphone, you can scan the QR code below to visit the website).

We need and would greatly appreciate your help.

Sincerely,

Scott Crosse, Ph.D.
PATH Study, Westat Director of Survey Operations
[PATH QR Code]

RS7d – Refusal Conversion Letters – Maximum Calls

<Date>

<Respondent Name>

<Address>

<Address>

Dear (Resident/[Respondent Name, if available]),

I understand that one of our interviewers has been trying to contact you about the Population Assessment of Tobacco and Health (PATH) study. This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). As the Director of Survey Operations, I'm writing to you personally to tell you about the importance of this study. I'm asking for your help.

Your participation in this study is important, whether or not you use tobacco. Your household was selected to represent many others like yours. Having every type of household in America take part in the study is very important. It helps us learn about the use of tobacco and its effects on health in the United States. What we learn should help improve the health of millions of Americans.

As a thank you for participating, we'll give you up to \$110, as we do for everyone who participates. I've enclosed a study brochure to help answer your questions. By participating, you'll be performing a valuable public service.

I've asked the interviewer to try to contact you again. If you have any questions or want to arrange a time for our interviewer to call you, please call our toll-free number, 1-800-xxx-xxxx, between 9:00 am and 5:30 pm Eastern Time. For information, you can also visit our website at [PATH URL] (if you have a smartphone, you can scan the QR code below to visit the website).

We need and would greatly appreciate your help.

Sincerely,

Scott Crosse, Ph.D.
PATH Study, Westat Director of Survey Operations

[PATH QR Code]

RS8 – Buccal Cell Collection Instructions

As part of the PATH study*, we ask you to collect cells from the inside of your cheek (buccal cells). We'll collect one sample using five scrapers. (Most people don't find this process painful or uncomfortable.)

Please review and follow the directions provided. If you have any questions, please ask.

***Note:* Don't put used scrapers back into your mouth.**

Instructions

1. Rinse your mouth with water three times.
 2. Using a scraper provided by the interviewer, scrape the inside of your *right* cheek using 10 quick strokes. Avoid touching your lips, and any sores, cuts, bleeding spots, etc. with the scraper, and be careful not to break your skin.
 3. Give the first used scraper to the interviewer.
 4. The interviewer will hand you a second scraper. Scrape the inside of your *left* cheek with 10 quick strokes.
 5. Give the second used scraper to the interviewer.
 6. The interviewer will hand you a third scraper. Scrape the inside of your *right* cheek with 10 quick strokes.
 7. Give the third used scraper to the interviewer.
 8. The interviewer will hand you a fourth scraper. Scrape the inside of your *left* cheek with 10 quick strokes.
 9. Give the fourth used scraper to the interviewer.
 10. The interviewer will hand you a fifth scraper. Use the fifth scraper to scrape one time on each cheek.
 11. Give the fifth used scraper to the interviewer.
-

If you have any questions, please ask the interviewer.

Thank you for providing this sample!

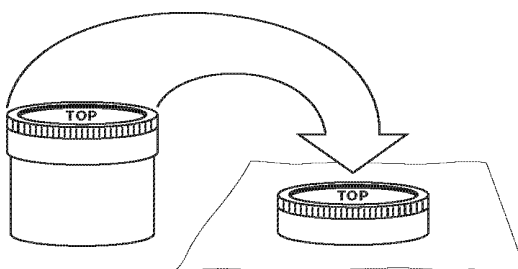
* This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

RS8a – Urine Collection Instructions

As part of the PATH study*, we ask you to collect a sample of your urine. Please follow these instructions.

Instructions

1. Wash your hands with soap and water.
2. Lay the paper towel in the kit on a flat surface. Take the lid off of the collection container and place it on the paper towel. The inside of the lid should be placed face down on the paper towel. Don't touch the inside of the lid or the inside of the collection container. Don't allow the inside of the lid or the inside of the collection container to come in contact with any part of your body, clothing, or bathroom surfaces.



3. Urinate directly into the container. Collect all of your urine; don't let any of it go into the toilet unless the container is full.
4. Replace the lid on the collection container immediately so that the urine is only briefly exposed to the air.
5. Use the paper towel to wipe any urine from the outside of the container.
6. Wash your hands with soap and water after collecting the sample.
7. Give the collection container back to the interviewer/phlebotomist.

If you have any questions, please ask the interviewer or phlebotomist.

Thank you for providing this sample!

* This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

RS8b – 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.

RS8c – 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.

RS8d – 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

RS9 – Hooper Holmes Brochure

Population Assessment of Tobacco and Health (PATH) Study Urine and Blood Collection

Thank you for agreeing to provide urine and blood samples for the PATH study. This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Please read this brochure to learn what happens next.

Step 1. Confirm your appointment. A Hooper Holmes phlebotomist will call you 1 to 2 days before your scheduled appointment. Hooper Holmes is a national provider of in-home blood collection services. The phlebotomist is a medical professional certified to draw blood and obtain other biological samples such as urine. The phlebotomist will call you to:

- Confirm the date and the time of your appointment, and your address.
- Remind you to drink water, at least eight ounces, just before the appointment if you are giving a urine sample.
- Remind you to record the date and time you last urinate before the appointment, if you are giving a urine sample.

Step 2. If you are giving a urine sample, you should record the date and time you last urinate before the scheduled appointment. Record this information on the appointment card or a piece of paper. You should also drink an eight ounce glass of water just before your appointment.

Step 3. The Hooper Holmes phlebotomist will come to your home on the appointed date and time. The phlebotomist will:

- Provide a driver's license and PATH study identification.
- Ask you several questions about your recent use of tobacco.
- Help with collection of your urine sample.
- Complete the blood collection in your home.

Step 3. One to two days after the sample collection is complete, you will receive your incentive.

- As a thank you for giving a urine sample, \$10 will be added to your PATH study debit card.
- As a thank you for giving a blood sample, \$30 will be added to your debit card.

Frequently Asked Questions

Why are you collecting urine and blood?

Urine and blood collection are critical to the success of the PATH study. Researchers will conduct tests on the blood that will help us to understand how tobacco affects the body. We are collecting samples from adults who use tobacco and those who do not..

How much blood will you take?

We'll collect six tubes of blood that equals about three tablespoons. The body makes blood daily and replaces this amount of blood within 24 hours.

Is it safe?

Yes. All PATH study phlebotomists have done more than 150 successful blood collections and have been trained and certified on PATH study collection procedures. The supplies used for blood collection are completely sterile and are used only once. You can't be infected by any bloodborne disease through this blood collection, such as hepatitis or AIDS.

Will I receive the results of the tests?

No. The results of the tests will be used for research purposes only, so we won't send individual test results to you.

Whom do I contact if I have questions about the blood or urine collection?

- Ask the interviewer or phlebotomist any questions you may have about the blood and urine collection; or
- Call (NAME, TITLE) at this PATH study toll-free number, [1-800-xxx-xxxx], between 9:00 am and 5:30 pm Eastern Time.

Whom do I contact if I want to change or confirm my appointment?

Call a Hooper Holmes Scheduling Coordinator at this toll-free number, [1-800-xxx-xxxx], to change or confirm your appointment.

RS10 – Incentive Receipt

Population Assessment of Tobacco and Health (PATH) Study Participant Receipt Form

Print Participant's Name:

Mr. / Mrs. / Ms. _____
(First) (MI) (Last)

The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) thank you for participating in the PATH study. Please accept **\$10** for participating in the screener interview, **\$60** for participating in the full interview, **\$10** for the urine collection, **\$10** for the cheek cell collection, and **\$30** for the blood collection.

- Payment of \$10 in cash has been made to the participant for the screener interview.
- Payment of \$60 on a debit card will be made to the participant for the full interview.
- Payment of \$10 on a debit card will be made to the participant for urine collection.
- Payment of \$10 on a debit card will be made to the participant for cheek cell collection.
- Payment of \$30 on a debit card will be made to the participant for blood collection.

By signing below, you acknowledge receipt of cash and/or a debit card that you will use for this study. Each time you participate in an interview or give a sample, we will make additional payments to you. Remember that participating in all or any part of the study is fully voluntary.

Participant's Signature:

Interviewer's Signature:

Date: ____ / ____ / ____

Date: ____ / ____ / ____

Note: Please allow 24 hours for your debit card to be activated. Your card will be active for 24 months. After 2 months, if any money is still on the card, a \$3 fee will be deducted from it each month. You will be charged \$1 for each bank teller cash withdrawal.

Please call our toll-free number, [1-800-xxx-xxxx], between 9:00 am and 5:30 pm Eastern Time, if you have concerns or questions.

RS11 – How to Get Help

Population Assessment of Tobacco and Health (PATH) Study*

How to Get Help

In today's visit, you expressed interest in learning about resources for one of these topics:

- Smoking/other tobacco use,
- Mental health, or
- Substance abuse.

Below is a list of telephone numbers and websites where you can get help and information on these topics. The list is not meant to be complete. You may also wish to first contact your family physician or your private health insurance provider for advice and referral.

Information on Smoking/Other Tobacco Use Resources

Smokefree.gov

Website: www.smokefree.gov

Telephone: 1-877-44U-QUIT (1-877-448-7848)

Smokefree.gov is a website created by the National Cancer Institute (NCI). The site offers the following information:

- Step-by-step quit guide,
- Talk to a smoking cessation expert at 1-877-448-7848,
- Tools to help you quit, and
- Topics related to quitting.

1-800-QUIT-NOW

Telephone: 1-800-QUIT-NOW (1-800-784-8669)

When you call 1-800-QUIT-NOW, you'll have access to many types of information and services about quitting smoking. They include

- Free support and advice from an experienced counselor,
- A personalized quit plan and self-help materials,
- Social support and coping strategies to help you deal with cravings, and
- The latest information about medications to help people quit smoking.

* This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

QuitNet

Website: www.quitnet.com

QuitNet is an online group of smokers and ex-smokers. Support comes from other people who share similar experiences in the effort to quit smoking. This approach is designed to help people help each other quit smoking using forums, chats, emails, and testimonials.

Information on Mental Health Resources

National Hopeline Network

Website: www.hopeline.com

Telephone: 1-800-SUICIDE (1-800-784-2433)

The Hopeline connects people in immediate distress to a crisis center. Calls are answered by certified counselors 24 hours a day, 7 days a week. When the system is fully operational, your call should be routed to a center nearest your home. A trained counselor should answer within two or three rings, or in about 20 to 30 seconds from the moment you dial 1-800-SUICIDE.

1-800-THERAPIST

Website: www.1-800-THERAPIST.com

Telephone: 1-800-843-7274

This is a toll-free number, and it's a free referral service. You can talk to a referral resource counselor during normal business hours. You must leave a message and someone will return your call. After an initial telephone evaluation, you can be referred to a full range of clinicians, including a psychiatrist, psychologist, marriage or family therapist, clinical social worker, licensed professional counselor, or nurse.

National Institute of Mental Health (NIMH) Public Inquiries

Website: www.nimh.nih.gov

Telephone: 301-443-4513

The public inquiries line is a toll call and is staffed by trained information specialists Monday through Friday, 8:30 am to 5:00 pm. (Eastern Time). Information is available on NIMH mental health research programs and on symptoms and treatment for emotional problems. NIMH does **not** provide referrals to health care providers or counsel people on specific problems. A list of NIMH publications, including several in Spanish, is available on the NIMH website at www.nimh.nih.gov. Single copies of these are free and may be requested by telephone at 301-443-4513, by fax at 301-443-4279, or by writing to NIMH Public Inquiries, 6001 Executive Blvd., Room 8184 MSC 9663, Bethesda, MD 20892-9663. Also, you can download publications directly from the website.

Information on Substance Abuse Resources

Substance Abuse and Mental Health Treatment (SAMHSA) Helpline

Website: www.samhsa.gov/treatment/

Telephone: 1-800-662-HELP (1-800-662-4357)

This treatment and referral system is a confidential, free, 24-hour-a-day, 365-days-a-year information service in English and Spanish for individuals and family members facing substance abuse and mental health issues. The service provides referrals to local treatment facilities, support groups, and community-based organizations. Callers can also order free publications (many are available for download) and other print information on substance abuse and mental health.

Parent Hotline

Website: www.parenthotline.net

Telephone: 1-800-840-6537

Parent Hotline has a website dedicated to helping families who are in a crisis. It lists behaviors for parents to be aware of, including drug use, and how to determine if a child is in need of intervention.

Libraries are an excellent source of information about these and other health concerns. Bookstores also often have relevant materials in their “diet and health” sections.

In addition, many websites have information related to these issues. Some are better than others. Knowing if the information on a site comes from sources you can trust is important. Be careful about sharing or exchanging information online, as some websites will not keep information private.

RS12 – Interview Appointment Card

PATH Study Interview Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]

PATH Study Interview Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]

PATH Study Interview Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]

PATH Study Interview Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]

Population Assessment of Tobacco and Health (PATH) Study

Interview Appointment

Just a reminder: I appreciate you taking time for this important study. I look forward to our appointment to complete the interview. We'll give you \$60, as a thank you for completing the interview. I have you scheduled for the following:

Day _____ Date _____ Time _____

Field Interviewer _____

We will call you to confirm the appointment.

Population Assessment of Tobacco and Health (PATH) Study

Interview Appointment

Just a reminder: I appreciate you taking time for this important study. I look forward to our appointment to complete the interview. We'll give you \$60, as a thank you for completing the interview. I have you scheduled for the following:

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We will call you to confirm the appointment.

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Day _____ Date _____ Time _____

Field Interviewer _____

We will call you to confirm the appointment.

Population Assessment of Tobacco and Health (PATH) Study

Interview Appointment

Just a reminder: I appreciate you taking time for this important study. I look forward to our appointment to complete the interview. We'll give you \$60, as a thank you for completing the interview. I have you scheduled for the following:

Day _____ Date _____ Time _____

Field Interviewer _____

We will call you to confirm the appointment.

RS13 – Phlebotomist Appointment Card

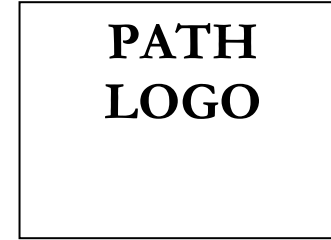
PATH Study Phlebotomist Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]
Hooper Holmes Scheduling Coordinator, 1-800-xxx-xxxx

PATH Study Phlebotomist Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]
Hooper Holmes Scheduling Coordinator, 1-800-xxx-xxxx

PATH Study Phlebotomist Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]
Hooper Holmes Scheduling Coordinator, 1-800-xxx-xxxx

PATH Study Phlebotomist Appointment



This study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA).

Westat, 1-800-xxx-xxxx, [PATH URL], [PATH QR Code]
Hooper Holmes Scheduling Coordinator, 1-800-xxx-xxxx

Population Assessment of Tobacco and Health (PATH) Study

Phlebotomist Appointment

Just a reminder: I appreciate you taking time for this important study. As a thank you, we'll give you \$10 for the urine sample and \$30 for the blood sample. I have you scheduled for the following:

Day _____ Date _____ Time _____

Record last urination before appointment:

Date: _____ Time: _____

The Hooper Holmes phlebotomist will contact you to confirm this appointment.

Population Assessment of Tobacco and Health (PATH) Study

Phlebotomist Appointment

Just a reminder: I appreciate you taking time for this important study. As a thank you, we'll give you \$10 for the urine sample and \$30 for the blood sample. I have you scheduled for the following:

Day _____ Date _____ Time _____

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Date: _____ Time: _____

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Record last urination before appointment:

Date: _____ Time: _____

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Day _____ Date _____ Time _____

Record last urination before appointment:

Date: _____ Time: _____

The Hooper Holmes phlebotomist will contact you to confirm this appointment.