



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
National Institutes of Health

DIVISION OF EPIDEMIOLOGY, SERVICES, AND PREVENTION RESEARCH

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DATE: May 8, 2015

TO: Office of Management and Budget (OMB)

Through: Report Clearance Officer, HHS
Project Clearance Chief, NIH
Project Clearance Liaison, NIDA

From: Kevin P. Conway, Ph.D., NIDA

SUBJ: Non-Substantive Change Request to Revise the Burden Estimates Approved by OMB for Wave 2 of the Population Assessment of Tobacco and Health (PATH) Study (OMB No. 0925-0664, Expiration Date 9/30/2016)

The National Institute on Drug Abuse (NIDA), in collaboration with its partner the Food and Drug Administration (FDA), requests OMB approval to replace pages 32 and 33 of Supporting Statement A (SSA) in the Revision Request approved by OMB on 9/8/2014 (ICR Reference No. 201407-0925-004) for Wave 2 of the Population Assessment of Tobacco and Health (PATH) Study. These pages are, respectively, Table A-3 (burden hour estimates) and Table A-4 (annualized cost estimates); they are corrected in Attachments D and E.

Revised Burden Estimates

The PATH Study's Revision Request for Wave 2 used projected Wave 1 sample sizes to estimate the Wave 2 sample sizes. Now that the counts of adults and youth participants in Wave 1 are complete (as of 3/31/15), it is possible to use them to update the projected sample size estimates in the Revision Request for Wave 2. In addition, the Revision Request underestimated the burden and associated respondent cost for the consent process for aged-up adults (i.e., new 18 year olds at Wave 2) and aged-up youth (i.e., new 12 year olds at Wave 2). Finally, the Revision Request for Wave 2 omitted estimated burden and respondent costs for the verification and validation interviews the PATH Study conducts.

In summary, this change request seeks OMB approval to correct the estimated burden and respondent cost associated with the updated sample size estimates for Wave 2 based on the final and complete samples sizes in Wave 1, the consent process for participants who have aged-up as either adults or as youth in Wave 2, and the verification and validation interviews.

The total estimated burden hours associated with this change request increase by 2,084 over the amount in the Wave 2 Revision Request and approved by OMB; the total respondent costs similarly increase, by \$37,980.

Details on each component of this request are provided below.

Updated Sample Size Estimates and Corrected Burden Hours for Consent for Wave 2. The sample size estimates in the Revision Request for Wave 2 were projected from the as-yet ongoing Wave 1. The actual (final) numbers of completed interviews for Wave 1 have since become available, indicating that more adults and fewer youth completed interviews in Wave 1 than originally estimated.

The differences between the projected and actual sample size estimates for Wave 2 are shown in Table 1, below. The first column shows the estimated sample sizes in the Revision Request for Wave 2 by type of respondent, *projected* from the corresponding numbers of completed interviews by type of respondent in Wave 1. The second column of Table 1 shows the estimated sample sizes for Wave 2 by type of respondent, but based on the *actual* numbers of completed interviews by type of respondent in Wave 1.

Table 1. Estimated sample sizes in the Revision Request for Wave 2 based on *projected* Wave 1 counts and revised sample size estimates based on *actual* Wave 1 counts

Type of respondent	Estimated sample sizes in Wave 2 Revision Request based on projected Wave 1 counts	Revised sample size estimates based on actual Wave 1 counts
Adults -- Baseline adult respondents	27,113	27,795
Adults - Baseline youth respondents who age into adult cohort	1,990	1,812
Subtotal	29,103	29,607
Youth -- Baseline youth respondents	10,537	10,048
Youth - Shadow youth respondents who age into adult cohort	2,105	2,007
Subtotal	12,642	12,055
Total	41,745	41,662

In preparing Wave 2 materials for printing, slight inconsistencies were found between the estimated burden in SSA (see Table A-3, page 32) for completion of four consent forms and the burden estimates appearing on the forms. In addition, recordings with over 10,000 participants from Wave 1 indicated that the burden for completing the four consent forms is slightly higher than the estimates shown for these in SSA of the Revision Request for Wave 2 (see Attachment A of this change request for the corrected English and Spanish versions of consent forms). This change request seeks OMB’s approval to make the same correction of the burden estimates for completion of the four consent forms in both SSA (see attached with corrected estimates) and on the forms (see attached replacement for Attachment 12, the consent materials).

Table 2, below, shows that, based on the actual (final) numbers for Wave 1 and including corrected burden hours for consent, the revised burden hour estimates increase by 674 hours over

the hours presented in the Revision Request for Wave 2 and approved by OMB; respondent costs increase by \$14,194.

Table 2. Wave 2 burden estimates for updated sample sizes and corrected consent forms

Type of respondent and instrument	Number of respondents	Frequency of response	Average time per respondent	Annual hour burden	Hourly wage rate	Respondent cost
Adults – Baseline adult respondents - Extended Interview	27,795	1	1	27,795	\$16.87	\$468,902
Adults – Baseline youth respondents who age into adult cohort – Consent for Extended Interview	2,090	1	4/60	139	\$16.87	\$2,345
Adults – Baseline youth respondents who age into the adult cohort -- Extended interview	1,812	1	68/60	2,054	\$16.87	\$34,651
Adults – Baseline youth respondents who age into the adult cohort -- Consent for Biological Samples	1,812	1	5/60	151	\$16.87	\$2,547
Adults – Biospecimen Collection: Urine	12,909	1	10/60	2,152	\$16.87	\$36,304
Adults – Biospecimen Collection: Blood	1,041	1	18/60	312	\$16.87	\$5,263
Adults – Tobacco Use Form	13,950	1	4/60	930	\$16.87	\$15,689
Adults – Follow-up/Tracking Participant Information Form	34,070	2	8/60	9,085	\$16.87	\$153,264
Youth – Extended Interview	10,048	1	32/60	5,359	\$7.25	\$38,853
Youth – Shadow youth who age into youth cohort -- Assent for Extended Interview	2,229	1	3/60	111	\$7.25	\$805
Youth – Shadow youth who age into youth cohort--youth Interview	2,007	1	42/60	1,405	\$7.25	\$10,186
Adult – Parent Interview	10,249	1	14/60	2,391	\$16.87	\$40,336

Type of respondent and instrument	Number of respondents	Frequency of response	Average time per respondent	Annual hour burden	Hourly wage rate	Respondent cost
Adults - Parents of Shadow youth who age into youth cohort - Parent Permission and Consent for Parent Interview	2,229	1	5/60	186	\$16.87	\$3,138
Adults - Parents of Shadow youth who age into youth cohort - Parent Interview	2,047	1	17/60	580	\$16.87	\$9,785
Adults - Follow-up/Tracking Participant Information Form for Youth (completed by parents)	13,836	2	8/60	3,690	\$16.87	\$62,250
Adults - Follow-up/Tracking Participant Information Form for sample Shadow youth (completed by parents)	4,772	2	8/60	1,273	\$16.87	\$21,476
Total				57,613		\$905,794

Verification and Validation Interviews in Wave 2. The PATH Study has been conducting verification and validation interviews since Wave 2 began on October 23, 2014 (see Attachments B and C of this change request for the forms that are used in Wave 2 for these interviews; the forms are listed in the revised SSA as new attachments 23, PATH Study Verification Form, and 24, PATH Study Validation Form, and they are referenced on page 7 of the revised SSA).

Briefly, the *verification interviews* are phone calls to adult Wave 1 participants before Wave 2 data collection to (a) confirm the participants still live at the most current home address, (b) identify another parent if the Wave 1 parent is no longer living with a youth participant, and (c) update contact information for adult participants and parents. They are primarily conducted by telephone. *Validation interviews* are phone calls to a random number of adults after completion of the Wave 2 extended interviews for purposes of confirming information recorded by field interviewers related to field interviewer performance. They, too, are primarily conducted by telephone.

Estimates of the burden hours and respondent costs for the two separate interviews were omitted from the Revision Request for Wave 2. Table 3, below, provides the estimated burden hours for both interviews (i.e., 1,410 hours) and the estimated respondent costs for both interviews (i.e., \$23,786).

Table 3. Estimated burden hours and respondent costs for verification and validation interviews in Wave 2

Type of respondent and instrument	Number of respondents	Frequency of response	Average time per respondent	Annual hour burden	Hourly wage rate	Respondent Cost
Adults -- Verification Interview	34,528	1	2/60	1,151	\$16.87	\$19,417
Adults -- Validation Interview	3,891	1	4/60	259	\$16.87	\$4,369
Total				1,410		\$23,786

Attachments

- A Revised PATH Study Consent Forms (included in revised, separate Attachment 12)
- B PATH Study Verification Form (included in new Attachment 23)
- C PATH Study Validation Form (included in new Attachment 24)
- D Table A-3. Corrected PATH Study Wave 2 hour burden estimates (see page 32 in attached, revised SSA)
- E Table A-4. Corrected PATH Study Wave 2 annualized cost to respondents (see page 33 in attached, revised SSA)

Attachment A PATH Study Revised Consent Forms

OMB Control Number 0925-0664
Expiration Date: 09/30/2016



Population Assessment of Tobacco and Health (PATH) Study Adult Interview Consent Form

Introduction

The Population Assessment of Tobacco and Health (PATH) Study is sponsored by the National Institutes of Health (NIH) in partnership with the Food and Drug Administration (FDA). Westat, an independent research firm, is conducting the study.

What is the purpose of the study?

The study will look at tobacco use and health in the U.S. population. You don't have to be a tobacco user to take part in the study. What we learn will help to improve the health of millions of Americans.

Why was I selected for this study?

Your household was selected by chance from a list of addresses. We selected you to represent many other people throughout the country.

Participation is voluntary. Because our information will be more useful and complete if you participate, we hope you'll agree to be part of the study.

What would you like me to do?

We'd like you to complete an interview using a computer. We'll ask about your attitudes, knowledge, and personal experiences with tobacco; we'll also ask about substance use, mental health, your relationships with friends and family, and your general health. You'll hear the interview questions in private, using headphones, and answer by touching a computer screen. You can skip any questions you don't want to answer. The questions take about 60 minutes to answer. After the interview, we'll ask you to participate in other activities, but you can say no.

The PATH Study will continue until November 2015 and perhaps longer. We'd like to interview you once a year until the study ends. We may also ask you to participate in other activities, but you can say no at any time.

Public reporting burden for this collection of information is estimated to average 4 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 (0925-0664). Do not return the completed form to this address.

We'll contact you occasionally to update your contact information, and we may send you letters and messages throughout the year. A Westat quality control person may call you to ask about your experience with the interviewer.

What other information will you collect?

We'll collect personal information, such as your name, address, and date of birth. We'll store this information in a highly secure location to protect it. We may use it to link to public health records, such as state and federal vital statistics records, and health and cancer registries. These registries are updated by state public health agencies to keep current information on the health status of patients who visit hospitals, clinics, laboratories, and doctors' offices.

Can I change my mind about participating?

Yes. You may refuse to participate in any interviews and you can stop at any time. If you don't participate or if you stop participating, you will not lose any benefits.

If you are in the study for a while and then stop, we won't ask for any more data from you. We would like to use the data already collected about you, unless you ask us not to. You will not be able to withdraw your data after the study has ended; until then, you may request that your data be destroyed.

What are the possible benefits and risks of participating in the study?

Participating in the study may not help you individually, but it may provide useful information on new ways to help protect the Nation's public health. The interview involves no risk of injury. The main risk, which is small, is your personal information or data could be revealed. We are taking several steps to protect your privacy and prevent that from ever happening.

How will you protect my privacy?

The researchers will do several things to protect your identity and the privacy of your data.

- We'll secure your personal information in a protected computer file.
- We'll secure your interview answers in a separate file.
- Your name will not appear on the interview. Your answers can only be linked to a number, not to your name. This means that your answers cannot be used to identify you.
- Your answers will be combined with answers from other adults in the study and secured in a protected computer file.
- We'll report on this information only for groups of people, not individuals.
- We'll destroy your personal information when the study is over.
- We won't put your personal information in any report about this study.

We've also obtained a legal document called a Certificate of Confidentiality. In this legal document, the Federal government certifies that PATH Study researchers can't be forced by any person or court of law to give your name with any of your answers. PATH Study researchers do have to give this information, if a project funded by NIH requests it for an audit or program review.

You may tell anyone you're participating in this study. We may provide your information to others if you have given them written permission to have it. Even though it is not what PATH Study researchers are studying, if we learn that you or someone else is harming you, your child, or others around you, we will report this to the police or a social services agency in your community to protect you or others.

Do I get anything for completing the interview?

Yes. You'll receive a \$35 debit card after you finish the interview this time as a thank you for participating. You can receive additional thank you gifts for participating in future interviews and other study activities. Also, each year you're in the study, you'll receive up to \$10 a year as a thank you for updating your contact information.

Can the sponsors stop this study?

Yes. If this happens, we will notify you.

Whom can I contact if I have further questions?

You can ask the interviewer any questions you have about the study.

If you have any questions about the study, call Westat's toll-free number, 1-888-311-1819, weekdays between 9:00 a.m. and 9:00 p.m. Eastern Time.

If you have any questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.

Do you have any questions now?

Consent signatures

By signing this form, you give your consent to participate in the PATH Study. This participation includes completing an interview and being contacted again to complete future interviews and possibly other study activities if you choose.

You give your consent to having the study securely maintain your personal information so that we can use it when we look at public health records, and state health and cancer registries.

You also authorize state cancer registries to release medical information about you to our researchers to learn about or confirm any cancer diagnosis in the future.

I have read the information about this study or someone has read it to me, and I have been given the chance to discuss it and to ask questions. I will receive a copy of this consent form for my records. I consent to take part in this study.

_____/_____/_____
Signature of Participant Month Day Year

Printed Name of Participant ID # of Interviewer

_____/_____/_____
Signature of Person Obtaining Consent Month Day Year

THANK YOU

OMB Control Number 0925-0664

Expiration Date: 09/30/2016



Evaluación Demográfica del Tabaco y la Salud o Estudio PATH

Formulario de consentimiento para entrevistas a adultos

Introducción

La Evaluación demográfica del tabaco y la salud (PATH, por sus siglas en inglés), está patrocinada por los Institutos Nacionales de la Salud (NIH, por sus siglas en inglés), en colaboración con la Administración de Alimentos y Medicamentos (FDA, por sus siglas en inglés). El estudio lo está realizando Westat, una compañía independiente de estudios de investigación.

¿Cuál es el propósito del estudio?

El estudio analizará el consumo del tabaco y la salud de la población en Estados Unidos. No tiene que ser un consumidor de tabaco para participar en el estudio. Los resultados nos ayudarán a mejorar la salud de millones de personas en Estados Unidos.

¿Por qué me eligieron para este estudio?

Su hogar fue elegido al azar de una lista de direcciones. Lo hemos elegido para que represente a muchas personas a nivel nacional.

Su participación es voluntaria. Esperamos que se anime a participar en el estudio ya que nuestra información será más completa y útil si usted participa.

¿Qué necesitan de mí?

Nos gustaría que hiciera una entrevista por medio de una computadora. Le haremos preguntas sobre sus opiniones, conocimientos y experiencias personales con el tabaco; además, le preguntaremos sobre el consumo de sustancias, como drogas y alcohol, la salud mental, sus relaciones con amigos y familiares y su salud en general. Escuchará las preguntas en privado, con audífonos, y las responderá al tocar la pantalla de la computadora. Puede dejar de responder las preguntas que desee. Le tomará unos 60 minutos responder las preguntas. Después de la entrevista le pediremos que participe en otras actividades, pero se puede negar.

Se estima que el cálculo de tiempo para esta recolección de información es de 4 minutos por cuestionario, incluyendo el tiempo necesario para revisar las instrucciones, buscar fuentes de datos existentes, reunir y mantener los datos necesarios y completar y revisar la recolección de información. Ninguna agencia puede realizar ni patrocinar una recolección de información, y ninguna persona está obligada a responder a dicha recolección de información, a menos que esta muestre un número de control vigente de la OMB. Envíe sus comentarios respecto a este cálculo de tiempo o a otro aspecto de esta recolección de información, incluyendo sugerencias de cómo reducir este cálculo de tiempo a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0664). No devuelva el cuestionario contestado a esta dirección.

El Estudio PATH continuará hasta noviembre del 2015 y posiblemente por más tiempo. Quisiéramos entrevistarle una vez al año hasta que el estudio termine. También le podríamos pedir que participe en otras actividades, pero se puede negar en cualquier momento.

Nos comunicaremos con usted de vez en cuando para actualizar su información de contacto y es posible que le enviemos cartas y otras informaciones durante el transcurso del año. Una persona encargada del control de calidad de Westat podría llamarle para preguntarle sobre su experiencia con el entrevistador.

Qué otro tipo de información recolectarán?

Recolectaremos información personal, tal como su nombre, su dirección y su fecha de nacimiento. Para proteger esta información, la mantendremos en un lugar altamente seguro. Es posible que usemos su información personal para relacionarla con registros públicos de salud, tales como los registros estatales y federales de estadísticas demográficas, registros de salud y de cáncer. Estos registros son actualizados por las agencias de salud pública del estado con el fin de disponer de información actual sobre el estado de salud de los pacientes que van a hospitales, clínicas, laboratorios y consultorios médicos.

¿Puedo cambiar mi decisión sobre mi participación?

Sí. Usted puede negarse a participar en cualquier entrevista y puede dejar de participar en cualquier momento. Si usted no participa o si deja de participar, no perderá ningún beneficio.

Si está en el estudio por un tiempo y luego lo deja, no le pediremos más información sobre usted. Nos gustaría utilizar la información ya recolectada, a menos que nos pida que no lo hagamos. No podrá retirar su información después de que el estudio haya terminado, pero hasta ese entonces, podrá solicitar que destruyan su información.

¿Cuáles son los posibles beneficios y riesgos de participar en el estudio?

Participar en el estudio no lo ayudará individualmente, pero podría proporcionar información útil sobre nuevas formas para ayudar a proteger la salud pública de la Nación. La entrevista no implica ningún riesgo de lesiones. El mayor riesgo es que su información personal o datos sean divulgados. Este riesgo es pequeño. Estamos tomando muchas medidas para proteger su privacidad y prevenir que eso suceda.

¿Cómo protegerán mi privacidad?

Los investigadores tomarán varias medidas para proteger su identidad y la confidencialidad de sus datos.

- Protegeremos su información personal en un archivo electrónico protegido en computadora.
- Protegeremos sus respuestas a la entrevista en un archivo por separado.
- Su nombre no aparecerá en la entrevista. Sus respuestas estarán relacionadas únicamente a un número, no a su nombre. Esto significa que no se utilizarán sus respuestas para identificarlo.
- Se combinarán sus respuestas con las respuestas de otros adultos participantes en el estudio y se guardarán en un archivo protegido en computadora.
- Informaremos los resultados por grupos de personas únicamente, no de manera individual.
- Al término del estudio, destruiremos su información personal.
- Su información personal no aparecerá en ninguno de los informes sobre este estudio.

Además, hemos obtenido un documento legal llamado Certificado de confidencialidad. En este documento legal, el gobierno federal certifica que los investigadores del tabaco y Estudio PATH no pueden ser forzados por ninguna persona o tribunal a dar su nombre con cualquiera de sus respuestas. Los investigadores del Estudio PATH deben proporcionar esta información si un proyecto patrocinado por los NIH lo solicita para una auditoría o para la revisión del programa.

Le puede decir a cualquiera que está participando en este estudio. Les podremos proporcionar su información a otras personas si usted les da una autorización por escrito. A pesar de que esto no es lo que el Estudio PATH está investigando, si descubrimos que usted u otra persona le está haciendo daño, a usted mismo, a su niño o a otras personas a su alrededor, se lo informaremos a la policía o a la agencia de servicio social de su comunidad para proteger a las personas a su alrededor o a usted mismo.

¿Obtendré algo por completar la entrevista?

Sí. Como agradecimiento por su participación, le daremos una tarjeta de débito por 35 dólares después de haber completado esta entrevista. Puede recibir incentivos adicionales como agradecimiento por participar en entrevistas futuras y otras actividades del estudio. Asimismo, cada año que

participe en el estudio, recibirá hasta 10 dólares al año como agradecimiento por actualizar su información de contacto.

¿Pueden los patrocinadores interrumpir el estudio?

Sí. Si eso ocurre, se lo informaremos.

¿A quién puedo contactar si tengo más preguntas?

Le puede hacer todas las preguntas que tenga sobre el estudio al entrevistador.

Si tiene alguna pregunta acerca del estudio, puede llamar a la línea directa y gratuita de Westat al 1-888-311-1819, entre semana, de 9:00 de la mañana a 9:00 de la noche, hora del Este.

Si tiene preguntas sobre sus derechos como participante del Estudio PATH, llame a la oficina en Westat de Protección de participantes en estudios, al 1-888-920-7631.

¿Tiene alguna pregunta en este momento?

Firmas de consentimiento

Al firmar este formulario, da su consentimiento para participar en el Estudio PATH. Esta participación incluye completar una entrevista, volver a ser contactado para completar entrevistas futuras y posiblemente participar en otras actividades del estudio si lo desea.

Da su consentimiento para que el estudio mantenga su información personal de manera segura para que podamos utilizar sus datos al buscar registros públicos de salud y registros estatales de salud y de cáncer.

También autoriza a los registros estatales de cáncer para que divulguen su información personal a nuestros investigadores para que puedan averiguar o confirmar algún diagnóstico futuro de cáncer.

He leído la información sobre este estudio o alguien me la ha leído y se me ha dado la oportunidad de hablar con el entrevistador y hacer preguntas sobre el estudio. Recibiré una copia de este consentimiento para mis registros. Doy mi consentimiento para participar en este estudio.

_____/_____/_____
Firma del participante Mes Día Año

Nombre del participante en letra de imprenta N° de identificación del entrevistador

_____/_____/_____
Firma de la persona que recibe el consentimiento Mes Día Año

GRACIAS

OMB Control Number 0925-0664

Expiration Date: 09/30/2016



A collaboration between the NIH and FDA

Population Assessment of Tobacco and Health (PATH) Study Parent Consent and Permission for Youth Interview Form

Name of Child _____

Introduction

The Population Assessment of Tobacco and Health (PATH) Study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). Westat, an independent research firm, is conducting the study.

What is the purpose of the PATH Study?

The PATH Study will look at the use of tobacco and how it may affect the health of people in the United States. What we learn will help to improve the health of millions of Americans. You don't have to be a tobacco user to take part in the study.

Why was my child selected for this study?

Your child was selected to take part in this study for two reasons. First, your household has been chosen by chance to represent many others like it in the country. Second, your child is in the 12- to 17-year-old age group being asked to participate in this study.

What information will I provide?

We'd like to ask you a few questions about your child before we ask his or her permission to do the interview. The questions will ask about your child's age and education, your relationship with your child, what your child knows and how he or she feels about tobacco, and any tobacco use.

The questions will take about 15 minutes to answer. Your participation is completely voluntary. If you do not want to participate, you will not lose any benefits. You may refuse to participate in this and any future interviews.

We are also asking your permission for your child to participate in the PATH Study.

Public reporting burden for this collection of information is estimated to average **5 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 (0925-0664). Do not return the completed form to this address.

What does my child's participation involve?

The interview asks your child questions about different areas of life, including his or her attitudes, knowledge, and personal experiences with tobacco. We will also ask about substance use, mental health, relationships with friends and family, and overall physical health.

The interview will be conducted in private and take about 40 minutes. Your child will use a computer, hear questions through headphones, and enter his or her answers directly into the computer by touching the screen. Your child can skip any questions he or she does not want to answer. You will not see your child's answers.

The PATH Study will continue until November 2015 and perhaps longer. We'd like your permission to interview your child now and once a year until the study is over. We may also ask your permission for you and your child to participate in other activities, but you can say no at any time.

We may contact you occasionally to update your contact information, and we may send you letters and messages throughout the year as reminders of the next visit. A Westat quality control person also may call you to ask about your experience with the interviewer.

When your child turns 18, he or she will be invited to enroll into the study as an adult and sign a consent form.

What other information will you collect?

Your child's personal information (such as name, address, date of birth) may be used in the future to get information from public health records, such as health registries, cancer registries, and vital statistics databases, on your child's health. Health registries are part of public health agencies that collect information from hospitals, clinics, laboratories, and doctors' offices.

We will protect your identity and your child's. Your child's personal information will be secured and will not be shared with anyone but a small group of qualified researchers who work on the study and will be destroyed when the PATH Study is over.

Can I or my child change our minds about participating?

Yes. You and your child may refuse to participate in any interviews and can stop at any time. If you don't want to participate or don't want your child to participate, you will not lose any benefits. Your child must also agree by signing a form that states he or she agrees to take part.

If you or your child stops, we won't ask for any more data. We would like to use the data already collected about you and your child unless you ask us not to. You will not be able to withdraw your data or your child's data after the study has ended, but until then, you may request that the data be destroyed.

What are the possible benefits and risks of participating in the study?

Participating in the study may not have a direct benefit to you or your child individually. Information from the study may benefit your community and the Nation by improving health strategies and programs.

If you or your child feels uncomfortable about any of the questions, it's OK to skip those questions. The main risk, which is small, is your answers or your child's answers could be revealed. We are taking steps to protect your privacy and your child's privacy, and to prevent this from ever happening.

How will you protect my privacy and my child's?

The study has safeguards in place to protect the identities of all participants, including yours and your child's. The information you provide will not be shared with your child; and information your child provides in the interview will not be shared with you, the child's school, or the authorities.

The researchers will take additional steps to protect your identity and your child's identity.

- We'll secure personal information in a protected computer file.
- We'll secure interview answers in a separate file.
- Your names will not appear on the interview. Your answers can only be linked to a number, not to your names. This means that your answers cannot be used to identify you or your child.
- Your answers will be combined with answers from others in the study and secured in a protected computer file.
- We'll report on this information only for groups of people, not individuals.
- We'll destroy your personal information and your child's when the study is over.
- We won't put your personal information in any report about this study.

Also, we've obtained a legal document called a Certificate of Confidentiality. In this legal document, the Federal government certifies that PATH Study researchers can't be forced by any person or court of law to give your name or your child's name with any of your answers. PATH Study researchers do have to give this information, if a project funded by NIH requests it for an audit or program review.

You and your child may tell anyone you're participating in this study. We may provide your information to others if you have given them written permission to have it. Even though it is not what PATH researchers are studying, if we learn that you or someone else is harming you, your child, or others around you, we will report this to the police or a social services agency in your community to protect you or others.

Will I or my child receive anything for completing the interview?

You will receive a \$10 debit card upon completion of the interview about your child and each future interview as a thank you for your participation.

Your child will receive a \$25 debit card upon completion of the youth interview and each future interview as a thank you for his/her participation. Also, each year your child is in the study, he/she will receive up to \$10 as a thank you when you update contact information for him/her.

Whom can I contact if I have further questions?

You can ask the interviewer any questions you have about this study.

If you have any questions about the study, call Westat's toll-free number, 1-888-311-1819, weekdays between 9:00 a.m. and 9:00 p.m. Eastern Time.

If you have any questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.

Do you have any questions now?

Consent signatures

By signing this form, you give your consent to answer questions about your child, and your permission for this interview and future interviews with your child. You also give your permission for the researchers to contact you regarding future interviews, and possibly other study activities with you and your child. Your child must also agree by signing a form. That form states that he or she agrees to take part but has the right to stop the interview at any time and may refuse to participate in this or any future interviews.

You give your consent to having the study securely maintain your child's personal information to access public health records in the future, and authorize state cancer registries to release medical information about your child to the researchers to learn about and confirm any cancer diagnosis in the future.

I have read the information about this study and have been given the chance to discuss it and to ask questions. I understand that my child must also agree to participate by signing a form. I understand I will receive a copy of this permission form for my records.

I agree to answer questions about my child. Yes No

I give permission for my child to take part in this study. Yes No

Signature of Parent/Guardian

_____/_____/_____
Month Day Year

Printed Name of Parent/Guardian

ID # of Interviewer

Signature of Person Obtaining Consent

_____/_____/_____
Month Day Year

THANK YOU

OMB Control Number 0925-0664

Expiration Date: 09/30/2016



A collaboration between the NIH and FDA

Evaluación Demográfica del Tabaco y la Salud o Estudio PATH Formulario de consentimiento de los padres y permiso para entrevistas a jóvenes

Nombre del niño o de la niña _____

Introducción

La Evaluación demográfica del tabaco y la salud (PATH, por sus siglas en inglés), está patrocinada por los Institutos Nacionales de la Salud (NIH, por sus siglas en inglés), en colaboración con la Administración de Alimentos y Medicamentos (FDA, por sus siglas en inglés). El estudio lo está realizando Westat, una compañía independiente de estudios de investigación.

¿Cuál es el propósito del Estudio PATH?

El Estudio PATH analizará el consumo del tabaco y cómo podría afectar la salud de las personas que viven en Estados Unidos. Los resultados nos ayudarán a mejorar la salud de millones de personas en Estados Unidos. No tiene que ser un consumidor de tabaco para participar en el estudio.

¿Por qué eligieron a mi niño para este estudio?

Eligieron a su niño para participar en este estudio por dos razones. Primero, su hogar fue elegido al azar para representar a muchos otros hogares como el suyo a nivel nacional. Segundo, su niño tiene entre 12 y 17 años y a este grupo de edad se le está pidiendo participación en el estudio.

¿Qué tipo de información quieren de mí?

Quisiéramos hacerle algunas preguntas sobre su hijo antes de pedirle a su hijo su autorización para hacer la entrevista. Las preguntas que haremos serán sobre la edad y la educación de su hijo, su relación con su hijo, acerca de lo que su hijo sabe y piensa respecto al tabaco y acerca de si su hijo consume tabaco.

Se estima que el cálculo de tiempo para esta recolección de información es de **5 minutos** por cuestionario, incluyendo el tiempo necesario para revisar las instrucciones, buscar fuentes de datos existentes, reunir y mantener los datos necesarios y completar y revisar la recolección de información. Ninguna agencia puede realizar ni patrocinar una recolección de información, y ninguna persona está obligada a responder a dicha recolección de información, a menos que esta muestre un número de control vigente de la OMB. Envíe sus comentarios respecto a este cálculo de tiempo o a otro aspecto de esta recolección de información, incluyendo sugerencias de cómo reducir este cálculo de tiempo a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0664). No devuelva el cuestionario contestado a esta dirección.

Le tomará unos 15 minutos responder las preguntas. Su participación es completamente voluntaria. Si no desea participar, no perderá ningún beneficio. Usted puede negar su participación en esta entrevista y cualquier entrevista futura.

También deseamos que nos dé su consentimiento para que su niño participe en el Estudio PATH.

¿En qué consiste la participación de mi niño?

En la entrevista se le preguntará a su niño sobre diversos aspectos de la vida, que incluyen sus opiniones, conocimiento y experiencias personales con el tabaco. Además, preguntaremos sobre el consumo de sustancias, como drogas y alcohol, la salud mental, las relaciones con amigos y familiares y la salud en general.

La entrevista se llevará a cabo en privado y tomará unos 40 minutos completarla. Su niño usará una computadora, escuchará las preguntas por medio de audífonos y anotará sus respuestas directamente al tocar la pantalla de la computadora. Su niño puede dejar de contestar cualquier pregunta que no desee contestar. Usted no verá las respuestas de su niño.

El Estudio PATH continuará hasta noviembre del 2015 y posiblemente por más tiempo. Quisiéramos contar con su permiso para entrevistar a su niño ahora y una vez al año hasta que el estudio termine. De vez en cuando nos comunicaremos con usted para actualizar su información de contacto, y le enviaremos cartas y otras informaciones durante el transcurso del año para recordarle la próxima visita. Además, una persona encargada del control de calidad de Westat podría llamarle para preguntarle sobre su experiencia con el entrevistador.

Cuando su niño cumpla 18 años, lo invitaremos para que se inscriba en el estudio como adulto y firme un consentimiento.

¿Qué otro tipo de información recolectarán?

La información personal de su niño (tal como su nombre, dirección, fecha de nacimiento) podría ser usada en el futuro para obtener información sobre la salud de su niño de registros de salud públicos, tales como registros de salud, de cáncer y de estadísticas demográficas. Los registros de salud forman parte de las agencias de salud públicas que recolectan información de hospitales, clínicas, laboratorios y consultorios médicos.

Mantendremos protegida su identidad y la de su niño. La información personal de su niño estará guardada de manera segura y no se compartirá con nadie más que un pequeño grupo de investigadores calificados que trabajan en el estudio y será destruida después de que el Estudio PATH haya terminado.

¿Puedo o puede mi niño cambiar la decisión sobre nuestra participación en el estudio?

Sí. Usted y su niño pueden negarse a participar en cualquier entrevista y pueden dejar de participar en cualquier momento. Si usted no desea participar o no desea que su niño participe, no perderán ningún beneficio. Su niño debe aceptar participar al firmar un consentimiento que diga que desea participar.

Si usted o su niño dejan de participar, no le pediremos más información. Nos gustaría utilizar la información ya recolectada acerca de usted y de su niño, a menos que nos pida que no lo hagamos. No podrá retirar su información o la de su niño después de que el estudio haya terminado, pero hasta ese entonces, podrá solicitar que destruyan la información.

¿Cuáles son los posibles beneficios y riesgos de participar en el estudio?

Participar en el estudio no lo beneficiará individualmente ni a usted ni a su niño. La información del estudio podría beneficiar a su comunidad y al país, al mejorar las estrategias y programas de salud.

Si usted o su niño no se sienten cómodos respondiendo algunas de las preguntas, pueden dejar de responderlas. El mayor riesgo, que es pequeño, es que su información personal o la de su niño sean divulgadas. Estamos tomando muchas medidas para proteger su privacidad y la de su niño, para prevenir que eso suceda.

¿Cómo protegerán mi privacidad y la de mi niño?

El estudio ha establecido medidas de seguridad para proteger la identidad de todos los participantes; esto incluye su identidad y la de su niño. La información que nos dé no será compartida con su niño; y la información que

su niño dé durante la entrevista no será compartida con usted, ni la escuela de su niño ni con otras autoridades.

Los investigadores tomarán medidas adicionales para proteger su identidad y la de su niño.

- Protegeremos la información personal en un archivo protegido en computadora.
- Protegeremos las respuestas a la entrevista en un documento por separado.
- Sus nombres no aparecerán en la entrevista. Sus respuestas estarán relacionadas únicamente a un número, no a sus nombres. Esto significa que no se utilizarán sus respuestas para identificarlo, ni a usted ni a su niño.
- Se combinarán sus respuestas con las respuestas de otros adultos participantes en el estudio y se guardarán en un archivo protegido en computadora.
- Informaremos los resultados por grupos de personas únicamente, no de manera individual.
- Al término del estudio, destruiremos su información personal y la de su niño.
- Su información personal no aparecerá en ninguno de los informes sobre este estudio.

Además, hemos obtenido un documento legal llamado Certificado de confidencialidad. En este documento legal, el gobierno federal certifica que los investigadores del Estudio PATH no pueden ser forzados por ninguna persona o tribunal a dar su nombre o el de su niño con cualquiera de sus respuestas. Los investigadores del Estudio PATH deben proporcionar esta información si un proyecto patrocinado por los NIH lo solicita para una auditoría o para la revisión del programa.

Usted y su niño le pueden decir a cualquiera que están participando en este estudio. Les podremos proporcionar su información a otras personas si usted les da una autorización por escrito. A pesar de que esto no es lo que PATH está investigando, si descubrimos que usted u otra persona le está haciendo daño, a usted, su niño o a otras personas a su alrededor, se lo informaremos a la policía o a la agencia de servicio social de su comunidad para proteger a las personas a su alrededor o a usted mismo.

¿Obtendré u obtendrá mi niño algo por completar la entrevista?

Como agradecimiento por su participación, usted recibirá una tarjeta de débito por 10 dólares una vez conteste la entrevista acerca de su hijo y cada vez que complete una entrevista en el futuro.

Le daremos una tarjeta de débito por 25 dólares a su niño, como agradecimiento por su participación, después de haber completado la entrevista de jóvenes y cada vez que complete una entrevista en el futuro. Asimismo, cada año que su niño participe en el estudio, él o ella recibirá hasta 10 dólares como agradecimiento por actualizar lo información de contacto de su niño.

¿A quién puedo contactar si tengo más preguntas?

Le puede hacer todas las preguntas que tenga sobre el estudio al entrevistador.

Si tiene alguna pregunta acerca del estudio, puede llamar a la línea directa y gratuita de Westat al 1-888-311-1819, entre semana, de 9:00 de la mañana a 9:00 de la noche, hora del Este.

Si tiene preguntas sobre sus derechos como participante del Estudio PATH, llame a la oficina en Westat de Protección de participantes en estudios, al 1-888-920-7631.

¿Tiene alguna pregunta en este momento?

Firmas de consentimiento

Al firmar este formulario, da su consentimiento para responder preguntas sobre su niño y da su autorización para hacer esta entrevista con su niño y completar entrevistas futuras con su niño. También da su consentimiento a los investigadores para que se comuniquen con usted con respecto a entrevistas futuras con su niño. Su niño también debe aceptar participar al firmar un consentimiento. Ese formulario indica que él o ella acepta participar en el estudio pero que tiene el derecho de dejar la entrevista en cualquier momento y puede negarse a participar en esta entrevista o en entrevistas futuras.

Da su consentimiento para que el estudio mantenga la información personal de su niño de manera segura para tener acceso a registros públicos de salud en el futuro, y autoriza a los registros estatales de cáncer para que divulguen la información médica de su niño a los investigadores con el fin de saber sobre cualquier diagnóstico futuro de cáncer o confirmarlo.

He leído la información sobre este estudio y se me ha dado la oportunidad de hablar con el entrevistador y hacer preguntas sobre el estudio. Entiendo que mi niño también debe aceptar participar al firmar un consentimiento. Además, entiendo que voy a recibir una copia de este consentimiento para mis registros.

Acepto responder preguntas sobre mi niño. Sí No

Doy mi autorización para que mi niño participe en este estudio. Sí No

Firma de los padres o tutores

_____/_____/_____
Mes Día Año

Nombre en letra de imprenta de los padres o tutores

N° de identificación del entrevistador

_____/_____/_____
Firma de la persona que recibe el consentimiento Mes Día Año

GRACIAS

OMB Control Number 0925-0664

Expiration Date: 09/30/2016



Population Assessment of Tobacco and Health (PATH) Study Youth Permission for Interview Form

Introduction

The Population Assessment of Tobacco and Health (PATH) Study is sponsored by the National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA). Westat, an independent research firm, is conducting the study.

This form describes what we'll be doing. Please read it or ask me to read it to you. Then, if you decide to be in the study, I'll ask you to sign the form.

Why are you doing this study?

We want to know more about tobacco and health in the United States. You don't have to be a tobacco user to take part in the study. What we learn from you and others in the study may help your community and millions of Americans to be healthier.

Why was I selected for this study?

We can't talk to every young person in America so we had to pick a smaller number of young people by chance to take part in the study. This means your answers will represent the answers that many other young people like you would give if they were in the study, too.

Your parent or guardian has given permission for you to participate.

What would you like me to do?

We'd like you to answer some questions on a computer. We call this an interview, even though you'll do it on a computer, rather than talking with another person. You'll listen to the questions on headphones. Your parents or guardians will not watch or see your answers. You'll answer the questions by touching the computer screen. The interview will take about 40 minutes to complete.

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 (0925-0664). Do not return the completed form to this address.

We'll ask about:

- What you think about tobacco use and tobacco advertising.
- What you know about tobacco.
- Your experiences with tobacco.
- Your friends' experiences with tobacco.
- Your life and your health.

You can skip any question you don't want to answer, and you can stop the interview at any time. You're in charge, but we hope you will answer all the questions because your answers are important.

The study will continue until November 2015 and perhaps longer. We will ask you questions once a year until the study ends. We may ask you to be part of other study activities, too, and you can decide if you want to or not. We'd like you to be part of the study even when you turn 18. We're studying adults, so when you turn 18, you can be in the adult part of the study.

What other information will you get about me?

We'll collect personal information, such as your name, address, and date of birth. We'll store this information in a highly secure location to protect it. We may use it to get information about you from public health records, such as health registries, cancer registries, and vital statistics databases. Health registries collect health information from hospitals, clinics, laboratories and doctors' offices.

We will protect your identity. Your personal information will not be shared with anyone but a small group of qualified researchers who work on the study and will be destroyed when the PATH Study is over.

Can I change my mind about being in this study?

Yes, you can say no or stop whenever you want. You or your family will not lose any benefits if you say no now or stop later. If you're in the study for a while and then stop, we would like to use the information you already gave us, unless you ask us not to. You will not be able to take back your information after the study is over; until then, you can ask that your information be destroyed.

Will anything good or bad happen to me if I'm in this study?

Being part of this study may not help you individually. However, the answers you give will be combined with the answers from many other young people and may help to improve the health of your community and millions of Americans.

The main bad thing that could happen is that people might find out personal information about you, but we have safeguards in place to keep this from happening.

How will you stop people from seeing my information?

We will keep your personal information, like your name and address, in a protected and secure computer file. We will keep your answers to the interview questions in a different file with answers from all the other people in the study.

This means:

- Your name will not be on your answers so people who work on the study will not know who you are.
- Your family will not know what you tell us and no one in your school or the authorities will know what you tell us.
- We will combine your answers with those from many other people in the study. We will report on this information only for groups of people, not individuals. This means we cannot put personal information about you in a report about the study.
- We will destroy your personal information when the study is over.

Also, we have a Certificate of Confidentiality. This means that no one doing the study can be forced to give anyone information about you, including your name. PATH Study researchers do have to give this information, if a project funded by NIH requests it for an audit or program review.

You may tell anyone you want that you're in this important study. Even though it is not what PATH researchers are studying, if we learn that you or someone else is harming you or others, we'll report this to the police or social services agency in your community to protect you or others.

Do I get anything for doing the interview?

Yes. You'll receive a \$25 debit card after you finish the interview this time and in future years as a thank you for participating. Also, each year you're in the study, you'll receive up to \$10 as a thank you when your parent updates your contact information.

Can the people in charge of this study stop it?

Yes. If this happens, we will tell you.

Is there someone I can talk to if I have more questions?

Yes. If you have questions now, you may talk to the interviewer.

If you have any questions about the study, call Westat's toll-free number, 1-888-311-1819, weekdays between 9:00 a.m. and 9:00 p.m. Eastern Time.

If you have questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631. This office that makes sure we're doing this study the right way.

Do you have any questions now?

Assent signatures

By signing this form, you agree to participate in the PATH Study and answer interview questions. You also agree to participate in future interviews and possibly in other activities if you choose.

You agree to let the study securely keep your personal information, so we can look for public health records in the future. You also agree to let state cancer registries give medical information about you to the study about any cancer diagnosis in the future.

I have read the information about this study or someone has read it to me. I have had a chance to talk about it and ask questions. I agree to take part in the study. I will get a copy of this form.

Signature of Participant

_____/_____/_____
Month / Day / Year

Printed Name of Participant

ID # of Interviewer

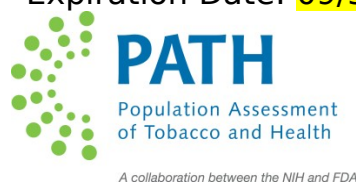
Signature of Person Obtaining Assent

_____/_____/_____
Month / Day / Year

THANK YOU

OMB Control Number 0925-0664

Expiration Date: 09/30/2016



Evaluación Demográfica del Tabaco y la Salud o Estudio PATH

Formulario de autorización para entrevistas a jóvenes

Introducción

La Evaluación demográfica del tabaco y la salud (PATH, por sus siglas en inglés), está patrocinada por los Institutos Nacionales de la Salud (NIH, por sus siglas en inglés), en colaboración con la Administración de Alimentos y Medicamentos (FDA, por sus siglas en inglés). El estudio lo está realizando Westat, una compañía independiente de estudios de investigación.

Este formulario describe lo que vamos a hacer. Por favor, léalo o dígame si necesita que se lo lea. Si decide participar en el estudio, le voy a pedir que firme el formulario.

¿Por qué se hace este estudio?

Queremos saber más sobre el consumo del tabaco y la salud en Estados Unidos. No tiene que ser un consumidor de tabaco para participar en el estudio. Lo que aprendamos de usted y de las otras personas en el estudio podría ayudar a su comunidad y a que millones de personas en Estados Unidos sean más saludables.

¿Por qué me eligieron para este estudio?

No podemos hablar con todos los jóvenes en Estados Unidos así que decidimos elegir un pequeño número de jóvenes al azar para que participen en el estudio. Esto significa que sus respuestas representarán las respuestas que muchos jóvenes como usted darían si también estuvieran participando en el estudio.

Su padre, madre o tutor ha dado la autorización para que pueda participar.

¿Qué necesitan de mí?

Nos gustaría que respondiera algunas preguntas en una computadora. A esto le llamamos una entrevista, a pesar de que usará una computadora en lugar de hablar con una persona. Escuchará las

Se estima que el cálculo de tiempo para esta recolección de información es de 3 minutos por cuestionario, incluyendo el tiempo necesario para revisar las instrucciones, buscar fuentes de datos existentes, reunir y mantener los datos necesarios y completar y revisar la recolección de información. Ninguna agencia puede realizar ni patrocinar una recolección de información, y ninguna persona está obligada a responder a dicha recolección de información, a menos que esta muestre un número de control vigente de la OMB. Envíe sus comentarios respecto a este cálculo de tiempo o a otro aspecto de esta recolección de información, incluyendo sugerencias de cómo reducir este cálculo de tiempo a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0664). No devuelva el cuestionario contestado a esta dirección.

preguntas a través de audífonos. Ni sus padres ni sus tutores verán sus respuestas. Contestará las preguntas tocando la pantalla de la computadora. Le tomará unos 40 minutos completar la entrevista.

Le preguntaremos sobre:

- lo que piensa del consumo de tabaco y los anuncios de tabaco.
- lo que sabe del tabaco.
- sus experiencias con el tabaco.
- las experiencias de sus amigos con el tabaco.
- su vida y su salud.

Puede dejar de responder cualquier pregunta que no desee responder y puede dejar de hacer la entrevista en cualquier momento. Usted está al mando, pero esperamos que responda todas las preguntas ya que sus respuestas son muy importantes.

El Estudio PATH continuará hasta noviembre del 2015 y posiblemente por más tiempo. Le haremos preguntas una vez al año hasta que el estudio termine. También le podríamos pedir participar en otras actividades del estudio, pero puede decidir si desea participar o no. Nos gustaría que sea parte del estudio aún después de cumplir 18 años. El estudio incluye a adultos también, así que cuando cumpla 18 años, podrá participar en el estudio como adulto.

¿Qué otro tipo de información recolectarán de mí?

Recolectaremos información personal, tal como su nombre, su dirección y su fecha de nacimiento. Para proteger esta información, la mantendremos en un lugar altamente seguro. Es posible que usemos su información personal para obtener información de registros de salud públicos tales como registros de salud, de cáncer y de estadísticas demográficas. Los registros de salud recolectan información de hospitales, clínicas, laboratorios y consultorios médicos.

Protegeremos su identidad. Su información personal no se compartirá con nadie aparte de un pequeño grupo de investigadores calificados que trabajan en el estudio y será destruida después de que el Estudio PATH haya terminado.

¿Puedo cambiar mi decisión sobre mi participación en este estudio?

Sí, se puede negar o puede dejar de participar cuando quiera. Ni usted ni su familia perderán ningún beneficio si se niega a participar ahora o deja de participar después. Si está participando en el estudio por un tiempo y luego lo deja, nos gustaría utilizar la información ya recolectada, a menos que nos pida que no lo hagamos. No podrá recuperar su información una vez que el estudio haya terminado; pero hasta ese entonces, puede pedir que se destruya su información.

¿Me pasará algo bueno o malo si participo en el estudio?

Participar en este estudio no lo ayudará individualmente. Sin embargo, las respuestas que dé se combinarán con las respuestas de muchos otros jóvenes participantes y podrían ayudar a mejorar la salud de su comunidad y de millones de personas en Estados Unidos.

Lo peor que le podría pasar es que alguien podría descubrir su información personal, pero hemos establecido medidas de seguridad para prevenir que esto ocurra.

¿Qué medidas tomarán para que otras personas no vean mi información?

Guardaremos su información personal, como su nombre y su dirección, asegurada en un archivo protegido en computadora. Mantendremos sus respuestas a las preguntas en un archivo distinto, junto con las respuestas de otras personas que participan en el estudio.

Esto significa que:

- Su nombre no aparecerá en sus respuestas para que las personas que trabajan en el estudio no sepan quién es.
- Su familia no sabrá lo que nos diga y nadie en su escuela ni las autoridades sabrán lo que nos diga.
- Combinaremos sus respuestas con las respuestas de muchas otras personas que participan en el estudio. Informaremos los resultados por grupos de personas únicamente, no de manera individual. Esto significa que no podemos incluir ninguna información personal suya en un informe sobre el estudio.
- Al término del estudio, destruiremos su información personal.

Además, tenemos un Certificado de confidencialidad. Esto significa que no pueden obligar a nadie que esté llevando a cabo el estudio a divulgar su información, incluido su nombre. Los investigadores del Estudio PATH deben proporcionar esta información si un proyecto patrocinado por los NIH lo solicita para una auditoría o para la revisión del programa.

Le puede decir a cualquiera que está participando en este importante estudio. A pesar de que esto no es lo que PATH está investigando, si descubrimos que usted u otra persona le está haciendo daño, a usted o a otras personas a su alrededor, se lo informaremos a la policía o a la agencia de servicio social de su comunidad para proteger a las personas a su alrededor o a usted mismo.

¿Obtendré algo por hacer la entrevista?

Sí. Como agradecimiento por su participación, le daremos una tarjeta de débito por 25 dólares después de haber completado esta entrevista y entrevistas futuras. Asimismo, cada año que participe en el estudio, recibirá hasta 10 dólares como agradecimiento cuando su padre o madre actualice su información de contacto.

¿Pueden las personas a cargo de este estudio interrumpirlo?

Sí. Si esto ocurre, se lo informaremos.

¿Hay alguien con quién pueda hablar si tengo más preguntas?

Sí. Si tiene preguntas en este momento, puede hablar con el entrevistador.

Si tiene alguna pregunta acerca del estudio, puede llamar a la línea directa y gratuita de Westat al 1-888-311-1819, entre semana, de 9:00 de la mañana a 9:00 de la noche, hora del Este.

Si tiene preguntas sobre sus derechos como participante del Estudio PATH, llame a la oficina en Westat de Protección de participantes en estudios, al 1-888-920-7631. Esta oficina se asegura que estamos realizando este estudio de manera correcta.

¿Tiene alguna pregunta en este momento?

Firmas de consentimiento

Al firmar este formulario, acepta participar en el Estudio PATH y responder las preguntas de la entrevista. También acepta participar en entrevistas futuras y, si lo desea, participar en otras actividades.

Da su consentimiento para que el estudio mantenga su información personal de manera segura, para poder utilizar sus datos al buscar registros públicos de salud en el futuro. Además, le da su autorización a los registros de cáncer para que divulguen su información médica al estudio sobre cualquier diagnóstico futuro de cáncer.

He leído la información sobre este estudio o alguien me la ha leído. Se me ha dado la oportunidad de hablar con el entrevistador y hacer preguntas sobre el estudio. Acepto participar en el estudio. Recibiré una copia de este consentimiento.

Firma del participante

_____/_____/_____
Mes Día Año

Nombre del participante en letra de imprenta

N° de identificación del entrevistador

Firma de la persona que recibe el consentimiento

_____/_____/_____
Mes Día Año

GRACIAS

OMB Control Number 0925-0664

Expiration Date: 09/30/2016



Population Assessment of Tobacco and Health (PATH) Study Consent for Biological Samples Pamphlet

The National Institutes of Health (NIH), in partnership with the Food and Drug Administration (FDA), is sponsoring the PATH Study. This study is one of the most important national health studies ever done in the United States. By participating, you are an essential part of what is learned about tobacco products and health.

In addition to an interview, we ask adults to give biological samples. These samples are critical to the success of the study. We need samples from both tobacco users and non-users.

For this part of the study, we'd like you to give us two kinds of biological samples:

- Urine and
- Blood (taken with sterile equipment by medically trained and certified health professionals).

This pamphlet tells you more about why we want these samples, explains what you need to do, discusses the risks and benefits of giving samples, and describes what you get for participating. After you've read this pamphlet or someone has read it to you, we will ask you to sign a form saying you agree to give samples.

Why do you want me to give you samples?

We can learn a lot more about tobacco products and health by combining information from samples and interviews. The samples give valuable information on these topics we can't get any other way. We will mainly test samples for chemicals associated with exposure to tobacco products and with health outcomes. We will not look for illegal drug use.

We will use information from samples and interviews for research purposes only. The study will keep this information private; it will only be seen by individuals working on the study.

Public reporting burden for this collection of information is estimated to average 5 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 (0925-0664). Do not return the completed form to this address.

If I say yes, what happens?

A PATH Study interviewer will come to your home once a year to interview you. At that time, the interviewer may ask you to give biological samples. Giving them is easy and quick; the interviewers and health professionals are trained to make you feel comfortable and respect your privacy.

- This year, and possibly in the future, the interviewer will ask you to give a urine sample; this takes about 10 minutes. It's just like giving a urine sample at your doctor's office.
- This year, and possibly in the future, we'll ask if a health professional can collect a sample of your blood. If you agree to give a blood sample, the interviewer will schedule an appointment for a medically trained and certified health professional to come to your home at a time that's convenient for you. This person will draw a small amount of blood (about 3 tablespoons) from your arm using sterile equipment. It's just like giving a blood sample at your doctor's office. It takes about 20 minutes.
- Each time you give a sample, we will ask questions about your recent use of tobacco products. This takes about 4 minutes.

Do I have to give you samples?

No. You decide whether to give us samples. You can decide to give us some samples but not others. Even if you don't give us samples, you can still be part of the PATH Study.

You can stop being part of the study at any time. If you stop, we'd like to keep the samples that you already gave us, but we'll destroy them if you tell us to.

Will you do research on my genes?

If you agree, we may use your samples for genetic research in the PATH Study and possibly in future studies. We'll look at how genes affect health among people who do and don't use tobacco products. We'll also look at how people's background and lifestyle—like age, education, and smoking—may work together with genes to affect their health.

If you don't want us to use your samples for genetic research, we'll only use them for other kinds of tests. These other tests are mainly for chemicals associated with exposure to tobacco products and with health outcomes.

Will I get the results of tests done on my samples?

You won't get the results of any tests done on your samples. Your results will be combined with results from other people in the study to help us understand the health of the general population.

How will you store my samples?

We'll ship your samples to a secure facility called a repository where they will be frozen and stored until they are tested. Your samples will be labeled with a code number only. This means your name won't be on the samples.

How long will you keep my samples?

If you agree that your samples can be used for research in the PATH Study and in future studies, we will keep your frozen samples at the repository for an unlimited period of time. We may keep using your samples for research unless you decide to withdraw your samples from the study or we close the secure repository where they are stored, at which time the samples will be destroyed.

What are the risks of providing samples?

- Giving us a urine sample has no risks.
- Giving a blood sample may hurt for a moment; rarely, it causes light-headedness, fainting, infection, bruising, hematoma, or bleeding. The health professionals who draw your blood are trained to make you feel comfortable and to make this a safe procedure.
- The risks from genetic research are very low. Only a code number will be on your samples, not your name. A Federal law (the Genetic Information Non-Discrimination Act, or GINA) will help make sure that health insurance companies or employers can't use what we find out from your genes.

Who will have access to my samples and data?

Only qualified researchers will have access to your samples. The PATH Study Biospecimen Access Committee will make sure these researchers are qualified and have procedures to protect the privacy of the results they get from your samples. These researchers won't be able to identify you because your name won't be on the samples. They will only have a code number on them.

How will you protect my privacy?

Your privacy is very important to the PATH Study.

- We'll treat all of the information in this study as private. The information will be used only for research purposes.
- We'll label your samples and interview answers with a code number only, not your name.
- We'll store your personal information in a protected computer file separate from your samples and the rest of your data. Your samples and data will only be identified by a code number. We'll keep the key to the code in a password-protected database.

- We'll combine your results with the results of the thousands of other people in the study. In addition, we'll only put information about groups of people in our reports. This means we can't put information about individuals in any report about the PATH Study.
- We'll destroy all personal information that could identify you, like your name, address, and phone number, after the study is over.

Also, we've obtained a legal document called a Certificate of Confidentiality. In this legal document, the Federal government certifies PATH Study researchers can't be forced by any person or court of law to give your name with any of your answers. PATH Study researchers do have to give this information, if a project funded by NIH requests it for an audit or program review.

You may tell anyone you're participating in this study. We may provide your information to others if you have given them written permission to have it. Even though it is not what PATH researchers are studying, if we learn that you or someone else is harming you, your child, or others around you, we will report this to the police or a social services agency in your community to protect you or others.

Do I get anything for providing samples?

Yes. In addition to the \$35 debit card for the interview, every year you provide samples you will get the following as a thank you:

- \$25 for your time providing a urine sample at a visit from an interviewer, and
- \$25 for your time providing a blood sample at a follow-up visit from a health professional.

What happens if I'm hurt as a result of taking part in this research?

You are not likely to get hurt while we are collecting your samples. Our procedures minimize any risks. If you are hurt, though, please see your doctor.

What are the costs to me?

Giving samples has no costs to you.

What if I have questions about the study?

You can ask the interviewer any questions you have right now. Do you have any questions now?

If you have any questions about the study, call Westat's toll-free number, 1-888-311-1819, weekdays between 9:00 a.m. and 9:00 p.m. Eastern Time.

If you have any questions about your rights as a PATH Study participant, call Westat's Human Subjects Protections office at 1-888-920-7631.

OMB Control Number 0925-0664

Expiration Date 09/30/2016



Una colaboración entre los NIH y la FDA

Estudio PATH (Evaluación demográfica del tabaco y la salud) Folleto para el consentimiento para muestras biológicas de adultos

Los Institutos Nacionales de la Salud (NIH, por sus siglas en inglés), en colaboración con la Administración de Alimentos y Medicamentos (FDA, por sus siglas en inglés), están patrocinando el Estudio PATH. Este estudio es uno de los más importantes estudios de salud a nivel nacional que se haya hecho en Estados Unidos. Su participación será una parte esencial de lo que aprendamos sobre los productos de tabaco y la salud.

Además de la entrevista, les pediremos a los adultos que den muestras biológicas. Estas muestras son muy importantes para el éxito del estudio. Necesitamos muestras de consumidores de tabaco al igual que de personas que no lo consumen.

Para esta parte del estudio, nos gustaría que nos diera dos tipos de muestras biológicas:

- de orina y
- de sangre (extraída con materiales esterilizados por un profesional de la salud certificado y con formación médica).

Este folleto le brinda más información acerca de por qué queremos estas muestras, le explica lo que tendrá que hacer, habla sobre los riesgos y beneficios de dar las muestras y le describe lo que obtendrá después de participar. Después de leer este folleto o de que alguien se lo haya leído, le pediremos que firme un formulario que dice que acepta dar muestras.

Se estima que el cálculo de tiempo para esta recolección de información es de 5 minutos por cuestionario, incluyendo el tiempo necesario para revisar las instrucciones, buscar fuentes de datos existentes, reunir y mantener los datos necesarios y completar y revisar la

recolección de información. Ninguna agencia puede realizar ni patrocinar una recolección de información, y ninguna persona está obligada a responder a dicha recolección de información, a menos que esta muestre un número de control vigente de la OMB. Envíe sus comentarios respecto a este cálculo de tiempo o a otro aspecto de esta recolección de información, incluyendo sugerencias de cómo reducir este cálculo de tiempo a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0664). No devuelva el cuestionario contestado a esta dirección.

¿Por qué quieren que les dé muestras?

Podemos aprender mucho más sobre los productos de tabaco y la salud al combinar la información obtenida mediante muestras y entrevistas. Las muestras proporcionan una valiosa información sobre estos temas que no podemos recolectar de otra manera. Principalmente, analizaremos las muestras para detectar la presencia de sustancias químicas que están relacionadas con la exposición a los productos de tabaco y con las consecuencias en la salud. No intentaremos detectar el consumo ilegal de drogas.

Utilizaremos la información de las muestras y de las entrevistas únicamente con fines de investigación. El estudio mantendrá la información en privado; solo la podrán ver las personas que trabajan en el estudio.

¿Qué pasa si acepto?

Un entrevistador del Estudio PATH irá a su hogar una vez al año para hacerle la entrevista. En ese entonces, el entrevistador podría pedirle que dé las muestras biológicas. Darlas es fácil y rápido; los entrevistadores y los profesionales de la salud están capacitados para hacerlo sentir cómodo y respetar su privacidad.

- Este año, y posiblemente en el futuro, el entrevistador le pedirá que dé una muestra de orina; esto toma unos 10 minutos. Es como dar una muestra de orina en el consultorio médico.
- Este año, y posiblemente en el futuro, le preguntaremos si un profesional de la salud puede recolectar una muestra de su sangre. Si acepta darnos una muestra de sangre, el entrevistador programará una cita para que un profesional de la salud licenciado y con formación médica vaya a su casa cuando le sea conveniente. Esta persona le sacará una pequeña cantidad de sangre (unas 3 cucharadas) de su brazo utilizando materiales esterilizados. Es como dar una muestra de sangre en el consultorio médico y toma unos 20 minutos.
- Cada vez que dé una muestra, le preguntaremos sobre su consumo reciente de productos de tabaco. Esto toma unos 4 minutos.

¿Le debo dar muestras?

No. Usted decide si desea dar muestras. Puede decidir darnos algunas muestras, pero no otras. Aún si no desea dar muestras, puede participar en el Estudio PATH.

Puede dejar de participar en el estudio en cualquier momento. Si deja de hacerlo, nos gustaría quedarnos con las muestras que ya nos dio, pero las destruiremos si nos lo pide.

¿Analizarán mis genes?

Si nos lo autoriza, podríamos usar sus muestras para estudios genéticos en el Estudio PATH y posiblemente en estudios futuros. Estudiaremos cómo los genes afectan la salud al comparar consumidores y no consumidores de productos de tabaco. Asimismo, analizaremos cómo los antecedentes de las personas y los aspectos de su estilo de vida—como la edad, la educación y el fumar—pueden colaborar para afectar la salud.

Si no desea que usemos sus muestras para estudios genéticos, las usaremos únicamente en otros tipos de pruebas. Estas otras pruebas se hacen principalmente para detectar la presencia de sustancias químicas que están relacionadas con la exposición a los productos de tabaco y con las consecuencias en la salud.

¿Recibiré los resultados de las pruebas hechas a mis muestras?

No recibirá ningún resultado de las pruebas hechas a sus muestras. Sus resultados se combinarán con los resultados de otras personas que participan en el estudio para ayudarnos a entender la salud de la población en general.

¿Cómo almacenarán mis muestras?

Enviaremos sus muestras a un establecimiento de alta seguridad, llamado repositorio, en donde sus muestras serán congeladas y almacenadas hasta que se hagan los estudios. Sus muestras se etiquetarán únicamente con un código numérico. Esto significa que su nombre no estará en las muestras.

¿Cuánto tiempo se quedarán con mis muestras?

Si usted acepta que sus muestras se usen en el Estudio PATH y en estudios futuros, mantendremos sus muestras congeladas en el repositorio por un periodo ilimitado. Es posible que sigamos usando sus muestras para estudios a menos que decida retirar sus muestras del estudio o que decidamos cerrar el repositorio seguro donde están guardadas. En este último caso, destruiremos las muestras.

¿Cuáles son los riesgos de dar muestras?

- Dar una muestra de orina no implica ningún riesgo.
- Dar muestras de sangre le podrá doler por un momento. Raras veces ocasiona mareos, desmayos, infecciones, moretones, hematomas o sangrado. Los profesionales de la salud que le toman la muestra de sangre están capacitados para hacerlo sentir cómodo y para hacer que este procedimiento sea seguro.

- Los riesgos de estudios genéticos son muy bajos. Sus muestras tendrán únicamente un código numérico, no tendrán su nombre. Una ley federal (Genetic Information Non-Discrimination Act [Ley No Discriminatoria de Información Genética] o GINA, por sus siglas en inglés) ayudará a cerciorarse que tanto las compañías de seguro como los empleadores no puedan usar los resultados de sus genes.

¿Quién tendrá acceso a mi información y mis muestras?

Investigadores calificados serán las únicas personas que tendrán acceso a sus muestras. El comité de acceso a muestras biológicas del Estudio PATH se asegurará de que los investigadores estén calificados y tengan procedimientos para proteger la privacidad de los resultados de sus muestras. Los investigadores no podrán identificarle ya que su nombre no aparecerá en ninguna de las muestras. Únicamente tendrán un código numérico.

¿Cómo protegerán mi privacidad?

Su privacidad es muy importante para el Estudio PATH.

- Mantendremos la información en este estudio en privado. Utilizaremos la información únicamente con fines de investigación.
- Sus muestras y las respuestas a la entrevista serán etiquetadas con un código numérico únicamente; no tendrán su nombre.
- Mantendremos su información personal protegida en un archivo de computadora; estará separada de sus muestras y del resto de su información. Tanto sus muestras como su información se podrán identificar únicamente por un código numérico. Mantendremos la clave del código en una base de datos protegida con contraseña.
- Combinaremos sus resultados junto con los resultados de miles de otras personas que participan en el estudio. Asimismo, incluiremos únicamente la información acerca de grupos de personas en nuestros informes. Esto significa que no podemos incluir información individual en cualquier informe acerca del Estudio PATH.
- Después de que haya terminado el estudio, destruiremos cualquier documento donde aparezca su información personal que pueda identificarle como su nombre, dirección y número de teléfono.

Además, hemos obtenido un documento legal llamado Certificado de confidencialidad. En este documento legal, el gobierno Federal certifica que los investigadores del Estudio PATH no pueden ser forzados por ninguna persona o tribunal a dar su nombre con cualquiera de sus respuestas. Los investigadores del Estudio PATH deben proporcionar esta información si un

proyecto patrocinado por los NIH lo solicita para una auditoría o para la revisión del programa.

Le puede decir a cualquiera que está participando en este estudio. Les podremos proporcionar su información a otras personas si usted les da una autorización por escrito para que la tengan. A pesar de que esto no es lo que PATH está investigando, si descubrimos que usted u otra persona le está haciendo daño, a usted mismo, a su niño o a otras personas a su alrededor, se lo informaremos a la policía o a la agencia de servicio social de su comunidad para proteger a las personas a su alrededor o a usted mismo.

¿Obtendré algo por dar muestras?

Sí. Además de la tarjeta de débito con 35 dólares, cada año que nos dé muestras recibirá lo siguiente en agradecimiento:

- 25 dólares por su tiempo para dar una muestra de orina durante la visita con el entrevistador y
- 25 dólares por su tiempo para dar las muestras de sangre en la visita de seguimiento del profesional de la salud.

¿Qué pasa si me lastimo por participar en este estudio?

No hay muchas probabilidades de que salga lastimado durante la recolección de muestras. Nuestros procedimientos reducen cualquier riesgo. Si se lastima, por favor visite a su médico.

¿Tengo que pagar algo?

No tiene que pagar nada para dar las muestras.

¿Qué pasa si tengo preguntas acerca del estudio?

Le puede hacer cualquier pregunta que tenga ahora al entrevistador. ¿Tiene alguna pregunta en este momento?

Si tiene alguna pregunta acerca del estudio, puede llamar a la línea directa y gratuita de Westat al 1-888-311-1819, entre semana, de 9:00 de la mañana a 9:00 de la noche, hora del Este.

Si tiene preguntas sobre sus derechos como participante del Estudio PATH, llame a la oficina en Westat de Protección de participantes en estudios, al 1-888-920-7631.

Attachment B PATH Study Verification Form

START

Program: Include the specifications below for each Wave 2 household unit, defined as:

(A) Sampled address from Wave 1 for which one or more SPs or Shadow Youth were selected to be in the study and completed a W1 interview and address is still best current address.

-OR-

(B) Address created since Wave 1 data collection closed and prior to fielding for W2 from instances when **all** (one or more) SPs and Shadow Youth originally at a W1 sampled address are found to have moved.

-OR-

(C) Address created during W2 based on Verification Task (VT) data collected at the Wave 2 fielded address and in which we determine one or more SPs has moved from the Wave 2 fielded address (either (A) or (B) above).

-OR-

(D) Address updated at the start of "this" Wave 2 VT based on new address/contact information received from another source, e.g. passed to the Field Interviewer (FI) via Case Alert or obtained via Field Tracing efforts.

(C) and (D) above identified as R02_AddressType = R02_NewVerify.

For each SP in the W2 fielded household unit, calculate Wave 2 Expected Event Type:

W2_ADULT, the SP was an Adult at Wave 1 and is an Adult at Wave 2.

W2_EXPECTEDADULT, the SP was a Youth at Wave 1 and is likely to age-in to the adult cohort either before or during Wave 2.

(HIS, SP Information, Age-in field = Yes or Maybe).

PROGRAM - Exception: If R02_AddressType = R02_NewVerify, for R02_W2_EXPECTEDADULT who was confirmed as 18+ in the original VT, set SP = W2_ADULT.

W2_YOUTH, the SP was a Youth or Shadow youth at Wave 1 and is likely a Youth/Shadow Youth at Wave 2.

Public reporting burden for this collection of information is estimated to average 2 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 (0925-0664). Do not return the completed form to this address.

PATH ID: R02_VTA00

Screen ID:

CONFIRM THAT YOU ARE SPEAKING WITH AN ADULT RESIDENT.

ARE YOU CONDUCTING THE VERIFICATION TASK BY TELEPHONE OR IN-PERSON?

- 1 TELEPHONE
- 7 IN-PERSON

ASK: All

PATH ID: R02_VTA00D

Screen ID:

May I please {verify/have} your full address?

IF ADDRESS IS SHOWN, READ ADDRESS ALOUD. VERIFY ALL SPELLING.

IF ADDRESS INFORMATION IS NOT SHOWN, RECORD FULL UPDATED ADDRESS.

STREET ADDRESS

CITY

STATE

ZIP

ASK: If new address collected in Wave 2 VT at fielded address.

PROGRAM: Pre-fill street address city, state, zip with address data collected from original case VT, User should be able to edit OR enter through each field. User should not be permitted to leave the Address Line 1, City, State or Zip fields blank.

PROGRAM: Pre-filled data may include only partial information available for address, e.g. City and State only.

PROGRAM: Display {have} if all address fields are empty (e.g. there is no address data to pre-fill to any of the fields). Else, display {verify},

PATH ID: R02_VTA01

Screen ID:

SELECT THE VERIFICATION TASK RESPONDENT.

- | | | |
|---|---|------------------|
| 1 | BASELINE HOUSEHOLD MEMBER 18+ FIRST NAME/
AGE/GENDER | GO TO BOX B |
| 2 | BASELINE HOUSEHOLD MEMBER 18+ FIRST NAME/
AGE/GENDER | GO TO BOX B |
| 3 | BASELINE HOUSEHOLD MEMBER 18+ FIRST NAME/
AGE/GENDER | GO TO BOX B |
| 4 | BASELINE HOUSEHOLD MEMBER 18+ FIRST NAME/
AGE/GENDER | GO TO BOX B |
| 5 | BASELINE HOUSEHOLD MEMBER 18+ FIRST
NAME /AGE/GENDER | GO TO BOX B |
| 6 | BASELINE HOUSEHOLD MEMBER 18+ FIRST
NAME /AGE/GENDER | GO TO BOX B |
| 7 | BASELINE HOUSEHOLD MEMBER 18+ FIRST
NAME /AGE/GENDER | GO TO BOX B |
| 8 | BASELINE HOUSEHOLD MEMBER 18+ FIRST
NAME /AGE/GENDER | GO TO BOX B |
| 9 | SPEAKING WITH SOMEONE ELSE | GO TO R02_VTA01B |

ASK: All.

ASK DESCRIPTION: Asked of all Wave 2 household units that meet (A), (B) (C) or (D) at Start.

PATH ID: R02_VTA01B

Screen ID:

ENTER FIRST AND LAST NAME OF THE VERIFICATION TASK RESPONDENT.

___ NAME ENTRY FIELDS GO TO R02_VTA01C

ASK: If selected SPEAKING WITH SOMEONE ELSE (9) at R02_VTA01.

ASK DESCRIPTION: Asked in instances when the FI needs to enter a new VT Respondent.

PATH ID: R02_VTA01C	Screen ID:
<p>What is the best telephone number to reach you?</p> <p>ENTER THE NUMBERS ONLY. DO NOT ENTER HYPHENS OR OTHER SYMBOLS.</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>___ PHONE NUMBER ENTRY FIELDS</p> </div> <div style="text-align: center;"> <p>GO TO BOX B</p> </div> </div> <p>ASK: If selected SPEAKING WITH SOMEONE ELSE (9) at R02_VTA01.</p> <p>ASK DESCRIPTION: Asked in instances when the FI needs to enter a new VT Respondent.</p>	

<p>BOX B</p> <p>Link Verification Task respondent selected in R02_VTA01 or entered in R02_VTA01B to the VT. Set R02_VT_R = respondent PID. If R02_VT_R is not assigned a respondent PID, set flag NewPersoninVT = 1 and set NewPersonTypeinVT = VT R.</p> <p>NAVIGATION: Go to Box 1.</p>
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<p>BOX 1</p> <p>Routing: If this VT is for a split address or this VT is being conducted with a VT Respondent who is a new person or this VT is being conducted with a VT Respondent who is a new parent from a previous VT, go to R02_VTA03_MV. Else, if this is a full household move address, go to R02_VTA02_MV. Else, go to Box 2.</p>
--

PATH ID: R02_VTA02_MV	Screen ID:						
<p>I'd like to confirm some information from my records. Were you living at {PROGRAM: INSERT ORIGINAL W1 SAMPLE ADDRESS} in {PROGRAM: INSERT MONTH/YEAR W1 PH1 SCREENER WAS COMPLETED}?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 50%;">YES</td> <td style="width: 40%; text-align: right;">GO TO R02_VTA03_MV</td> </tr> <tr> <td style="text-align: center;">2</td> <td>NO</td> <td style="text-align: right;">GO TO R02_VTA02B_MV</td> </tr> </table> <p>ASK: Ask in all instances when the address is not an original Wave 1 sampled address. In other words, the address was added due to one or more SPs/Parents moving, as per (B) or (C) above.</p>		1	YES	GO TO R02_VTA03_MV	2	NO	GO TO R02_VTA02B_MV
1	YES	GO TO R02_VTA03_MV					
2	NO	GO TO R02_VTA02B_MV					

PATH ID: R02_VTA02B_MV	Screen ID:						
<p>Did you ever live at {PROGRAM: INSERT ORIGINAL W1 SAMPLE ADDRESS}?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 40%;">YES</td> <td style="width: 50%; text-align: right;">GO TO R02_VTA02C_MV</td> </tr> <tr> <td style="text-align: center;">2</td> <td>NO</td> <td style="text-align: right;">GO TO R02_VTA02D_MV</td> </tr> </table> <p>ASK: Ask in all instances when the VT Respondent has indicated that he/she was not living at the original W1 sampled address in the month/year when the baseline Ph1 screener was completed.</p>		1	YES	GO TO R02_VTA02C_MV	2	NO	GO TO R02_VTA02D_MV
1	YES	GO TO R02_VTA02C_MV					
2	NO	GO TO R02_VTA02D_MV					

PATH ID: R02_VTA02C_MV	Screen ID:						
<p>When did you last live there?</p> <p>ENTER MONTH AND YEAR RESPONDENT REPORTS LAST LIVING AT {PROGRAM: INSERT ORIGINAL W1 SAMPLE ADDRESS}.</p> <p>ENTER MONTH: ENTER YEAR:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"></td> <td style="width: 40%; text-align: center;">ENTER MONTH</td> <td style="width: 50%; text-align: right;">GO TO R02_VTA02C_MVYR</td> </tr> <tr> <td></td> <td style="text-align: center;">ENTER YEAR</td> <td style="text-align: right;">GO TO BOX 1B</td> </tr> </table> <p>ASK: Ask in all instances when the VT Respondent reports living at the W1 sample address, but not in the month/year indicated.</p>			ENTER MONTH	GO TO R02_VTA02C_MVYR		ENTER YEAR	GO TO BOX 1B
	ENTER MONTH	GO TO R02_VTA02C_MVYR					
	ENTER YEAR	GO TO BOX 1B					

BOX 1B							
<p>DISPLAY HARD ERROR:</p> <p>YOU HAVE RECORDED THAT THE RESPONDENT LAST LIVED AT {PROGRAM: INSERT ORIGINAL W1 SAMPLE ADDRESS} ON A DATE THAT DOES NOT MATCH THE BASELINE DATA COLLECTION PERIOD.</p> <p>PRESS S IF YES.</p> <p>PRESS G TO GO BACK AND EDIT ENTRY.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">S</td> <td style="width: 40%;">SUPRESS</td> <td style="width: 50%; text-align: right;">GO TO BOX 1C</td> </tr> <tr> <td style="text-align: center;">G</td> <td>GO BACK</td> <td style="text-align: right;">GO TO R02_VTA02C_MV</td> </tr> </table> <p>Program: Display Box 1B if Month and Year indicated is not between (inclusive of) June 2013 and January 2015.</p>		S	SUPRESS	GO TO BOX 1C	G	GO BACK	GO TO R02_VTA02C_MV
S	SUPRESS	GO TO BOX 1C					
G	GO BACK	GO TO R02_VTA02C_MV					

BOX 1C	
<p>PROGRAM LOGIC CHECK:</p> <p>Run logic check to see if date VT R reports living at W1 sampled address in R02_VTA02C_MV is in the period of (inclusive of) June 2013 and January 2015. If matches, go to R02_VTA03_MV. If date does not fall in the time period indicated, go to Box 2.</p>	

PATH ID: R02_VTA02D_MV

Screen ID:

At what address were you living in {PROGRAM: INSERT MONTH/YEAR W1 PH1 SCREENER WAS COMPLETED}?

STREET ADDRESS, CITY, STATE, ZIP

NAVIGATION: GO TO BOX 2.

ASK: in all instances when the VT Respondent reports not living at the W1 sample address in the Month/Year the Ph1 screener was done and not ever living at the W1 sample address.

PATH ID: R02_VTA03_MV

Screen ID:

PROGRAM: VTA03_MV screen display, except when Scrn101_NumofPeople = 1):

Can you give me the name of one person who was living {with you} at {PROGRAM: INSERT ORIGINAL W1 SAMPLE ADDRESS} in {PROGRAM: INSERT MONTH/YEAR W1 PH1 SCREENER WAS COMPLETED}?

PROGRAM: LIST DISPLAY OF ALL WAVE 1 ENUMERATED PERSONS AT LINKED W1 SAMPLE ADDRESS.

BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
BASELINE HOUSEHOLD MEMBER
NAME/AGE/GENDER
SP LIVED ALONE AT BASELINE

DID RESPONDENT PROVIDE THE NAME OF ONE OF THE PEOPLE IN THE LIST?

- 1 YES GO TO BOX 2
- 2 NO GO TO BOX 2

ASK: Ask in all instances when the VT Respondent confirmed he/she was living at the W1 sampled address or in instances when the VT Respondent reports 'ever living' at W1 sample address in the time period in Box 1B. Or, ask in all instances when this is a VT for a split address, or the VT Respondent for this VT is a new person, or the VT Respondent for this VT is a new parent from a previous VT.

SP LIVED ALONE AT BASELINE.

PRESS 1 (YES) TO CONTINUE.

- 1 YES GO TO BOX 2
- 2 NO GO TO BOX 2

ASK: Ask in all instances when the VT R confirmed he/she was living at the W1 sampled address or in instances when the VT R reports 'ever living' at W1 sample address in the time period in Box 1B. Or, ask in all instances when this is a VT for a split address.

BOX 2

PROGRAM LOGIC CHECK:

- 1 IDENTITY VERIFIED GO TO R02_VTA04
- 2 IDENTITY NOT VERIFIED GO TO R02_VTA03B_MV

PATH ID: R02_VTA03B_MV

Screen ID:

Thank you. I am not sure whether my records are correct. I will check the information you have given me against my records and get back to you.

PRESS 1 TO CONTINUE.

1 EXIT

END

ASK: Ask in all instances when data entered in the route from R02_VTA02 through Box 2 does not verify.

PROGRAM: END Verification Task. Return to IMS. Set Verification Task to IRW (Interim Review). Require FS/HO direction before FI can continue. Do not enable any subsequent SP tasks.

PATH ID: R02_VTA04	Screen ID:		
<p>We would like your help in getting some updated contact information for {you and the other PATH Study participant(s)/ each PATH Study participant}.</p> <p>PROGRAM: List Display all W1 Adult, Youth, Shadow Youth in list format, in age descending order now associated with W2_LINKED_ADDRESS.</p> <p>{ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>PRESS 1 TO CONTINUE.</p> <table style="width: 100%;"> <tr> <td style="text-align: center;">1 CONTINUE</td> <td style="text-align: center;">GO TO START LOOP</td> </tr> </table> <p>ASK DESCRIPTION: (If IDVERIFIED = 1) and (household had at least one SP other than VT Respondent at W1). (If the W2_LINKED_ADDRESS has only one SP and the SP = VT R. Skip R02_VTA04 and go to R02_VTA05.)</p>		1 CONTINUE	GO TO START LOOP
1 CONTINUE	GO TO START LOOP		

START LOOP
PROGRAM: For each name in list in R02_VTA04, ask items R02_VTA05 through R02_VTA40, following skips as appropriate, then returning to R02_VTA05 for the next SP in list. While asking questions in the route for one SP instance (defined as SP N), continue to display associated SP name/age/gender on all screens along the route. Once instrument transitions to the next SP in list (defined as SP, N+1), display SP name/age/gender for SP N+1. Ask questions about all SPs in the same order as shown in the List Display in R02_VTA04: age descending where age = R02_CURRENT_AGE_LD. Continue until data is obtained for all SP instances. Create response panel with all persons in List Display in R02_VTA04; display one person's data per row.

PATH ID: R02_VTA05	Screen ID:				
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>{I'd like to update {your/SP Name's} contact information for my records.}</p> <p>{Are you/Is NAME} still living at {PROGRAM: INSERT W2_LINKED_ADDRESS}?</p> <p>{[We will not contact anyone under the age of 18 without first speaking to an adult or parent.]}</p> <table style="width: 100%;"> <tr> <td style="text-align: center;">1 YES</td> <td style="text-align: center;">GO TO BOX 3</td> </tr> <tr> <td style="text-align: center;">2 NO</td> <td style="text-align: center;">GO TO R02_VTA10</td> </tr> </table> <p>ASK: Ask in instances when associated address is W1 sample address (SampleID = any), or in instances of partial/full movers, if the identity of the Respondent at the new address has been verified earlier in this instrument.</p>		1 YES	GO TO BOX 3	2 NO	GO TO R02_VTA10
1 YES	GO TO BOX 3				
2 NO	GO TO R02_VTA10				

PATH ID: BOX 3	Screen ID:
<p>If SP is W2_ADULT, go to Box 6B. Else if SP=W2_EXPECTEDADULT, go to R02_VTA20. Else, if SP=W2_YOUTH, go to Box 6A.</p>	

PROGRAM – Exception: If R02_AddressType = R02_NewVerify, change any W2_EXPECTEDADULT confirmed as 18+ in previous VT to W2 Expected Event Type = W2_ADULT, and go to Box 6B.

PATH ID: R02_VTA10	Screen ID:									
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>Did {you/NAME} move or is there another reason why {you are/he is/she is} no longer at this address?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 50%;">MOVED</td> <td style="width: 40%;">GO TO Box 4</td> </tr> <tr> <td style="text-align: center;">7</td> <td>DECEASED</td> <td>GO TO R02_VTA14</td> </tr> <tr> <td style="text-align: center;">9</td> <td>ANOTHER REASON</td> <td>GO TO R02_VTA16</td> </tr> </table> <p>ASK: If any SPs reported to have moved from the W2_LINKED_ADDRESS in R02_VTA05.</p>		1	MOVED	GO TO Box 4	7	DECEASED	GO TO R02_VTA14	9	ANOTHER REASON	GO TO R02_VTA16
1	MOVED	GO TO Box 4								
7	DECEASED	GO TO R02_VTA14								
9	ANOTHER REASON	GO TO R02_VTA16								

PATH ID: BOX 4	Screen ID:
<p>If this is the first SP instance for which R02_VTA10 = 1 and asking about the Verification Task Respondent, go to R02_VTA12. Or, if this is the first SP instance for which R02_VTA10 = 1 and this SP instance != VT R, go to R02_VTA11.</p> <p>If this is not the first SP instance (first SP in Loop) for which R02_VTA10 = 1, go to R02_VTA10X.</p>	

PATH ID: R02_VTA10X	Screen ID:																											
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>Did {NAME} also move to (READ POSSIBLE ADDRESSES)?</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 50%;">MOVED TO {INSERT R02_MOVED ADD01}</td> <td style="width: 40%;">GO TO Box 4B</td> </tr> <tr> <td style="text-align: center;">2</td> <td>MOVED TO {INSERT R02_MOVED ADD02}</td> <td>GO TO Box 4B</td> </tr> <tr> <td style="text-align: center;">3</td> <td>MOVED TO {INSERT R02_MOVED ADD03}</td> <td>GO TO Box 4B</td> </tr> <tr> <td style="text-align: center;">4</td> <td>MOVED TO {INSERT R02_MOVED ADD04}</td> <td>GO TO Box 4B</td> </tr> <tr> <td style="text-align: center;">5</td> <td>MOVED TO {INSERT R02_MOVED ADD05}</td> <td>GO TO Box 4B</td> </tr> <tr> <td style="text-align: center;">6</td> <td>MOVED TO {INSERT R02_MOVED ADD06}</td> <td>GO TO Box 4B</td> </tr> <tr> <td style="text-align: center;">7</td> <td>MOVED TO {INSERT R02_MOVED ADD07}</td> <td>GO TO Box 4B</td> </tr> <tr> <td style="text-align: center;">8</td> <td>ENTER DIFFERENT ADDRESS</td> <td>GO TO R02_VTA12</td> </tr> <tr> <td style="text-align: center;">9</td> <td>DON'T KNOW/REFUSE</td> <td>GO TO R02_VTA13</td> </tr> </table> <p>ASK: Ask of subsequent SP instances (after the first SP in Loop has found to have moved) for which R02_VTA10 = 1.</p>		1	MOVED TO {INSERT R02_MOVED ADD01}	GO TO Box 4B	2	MOVED TO {INSERT R02_MOVED ADD02}	GO TO Box 4B	3	MOVED TO {INSERT R02_MOVED ADD03}	GO TO Box 4B	4	MOVED TO {INSERT R02_MOVED ADD04}	GO TO Box 4B	5	MOVED TO {INSERT R02_MOVED ADD05}	GO TO Box 4B	6	MOVED TO {INSERT R02_MOVED ADD06}	GO TO Box 4B	7	MOVED TO {INSERT R02_MOVED ADD07}	GO TO Box 4B	8	ENTER DIFFERENT ADDRESS	GO TO R02_VTA12	9	DON'T KNOW/REFUSE	GO TO R02_VTA13
1	MOVED TO {INSERT R02_MOVED ADD01}	GO TO Box 4B																										
2	MOVED TO {INSERT R02_MOVED ADD02}	GO TO Box 4B																										
3	MOVED TO {INSERT R02_MOVED ADD03}	GO TO Box 4B																										
4	MOVED TO {INSERT R02_MOVED ADD04}	GO TO Box 4B																										
5	MOVED TO {INSERT R02_MOVED ADD05}	GO TO Box 4B																										
6	MOVED TO {INSERT R02_MOVED ADD06}	GO TO Box 4B																										
7	MOVED TO {INSERT R02_MOVED ADD07}	GO TO Box 4B																										
8	ENTER DIFFERENT ADDRESS	GO TO R02_VTA12																										
9	DON'T KNOW/REFUSE	GO TO R02_VTA13																										

PATH ID: R02_VTA11	Screen ID:									
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>OBTAIN A NEW ADDRESS FOR (ADULT/YOUTH/SHADOW YOUTH) NAME ONLY IF THIS IS A MOVE.</p> <p>Do you know {PROGRAM: INSERT SP NAME}'s current address?</p> <p>{{Right now, I am just looking to update my records. We will not contact anyone under the age of 18 without first speaking to an Adult.}}</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 50%;">YES</td> <td style="width: 40%;">GO TO R02_VTA12</td> </tr> <tr> <td style="text-align: center;">7</td> <td>NO</td> <td>GO TO R02_VTA13</td> </tr> <tr> <td style="text-align: center;">9</td> <td>DON'T KNOW/REFUSE</td> <td>GO TO R02_VTA13</td> </tr> </table>		1	YES	GO TO R02_VTA12	7	NO	GO TO R02_VTA13	9	DON'T KNOW/REFUSE	GO TO R02_VTA13
1	YES	GO TO R02_VTA12								
7	NO	GO TO R02_VTA13								
9	DON'T KNOW/REFUSE	GO TO R02_VTA13								

ASK: Ask the Verification Task respondent of all Wave 1 SPs displayed in the List Display in R02_VTA04. Do not ask this question of the VT respondent.

PATH ID: R02_VTA12	Screen ID:
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>OBTAIN A NEW ADDRESS FOR (ADULT/YOUTH/SHADOW YOUTH} NAME ONLY IF THIS IS A MOVE.</p> <p>What is {your/NAME}'s address?</p> <p>{{Right now, I am just looking to update my records. We will not contact anyone under the age of 18 without first speaking to an adult.}}</p> <p>PROGRAM: DISPLAY AND LABEL ADDRESS FIELDS: STREET ADDRESS, CITY, STATE, ZIP</p> <p>NAVIGATION: GO TO BOX 4B.</p> <p>ASK: Ask in instances when the VT Respondent has self-reported a move or reported other W1 SPs have moved and he/she knows the new address.</p> <p>PROGRAM: Derive new variable, R02_MOVEDADD0n and populate R02_MOVEDADD0n with the new address obtained in R02_VTA12. Up to 7 new addresses can be created.</p>	

PATH ID: R02_VTA13	Screen ID:
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>Could you provide any information you may have about where {NAME} is now living, such as the city or state?</p> <p>PROBE FOR AS MUCH DETAIL AS POSSIBLE.</p> <p>DOCUMENT ANY INFORMATION PROVIDED ABOUT WHERE THE SP HAS MOVED.</p> <p>PROGRAM: DISPLAY TEXT FIELD, MAX CHARACTER LENGTH = 250. Make sure response box is large enough for user to see sufficient amount of typed free text.</p> <p>NAVIGATION: GO TO BOX 5.</p> <p>ASK: If R02_VTA11 = 7 or 9 (or) R02_VTA10X = 9.</p>	

PATH ID: BOX 4B	Screen ID:
<p>PROGRAM: Retain new address collected in first (and all previous) SP instance(s) in R02_VTA12 . Then, create/add to array of moved addresses that is asked/displayed in subsequent SP instances (N+1).</p> <p>Create a new variable for each new unique moved address, up to 7, obtained:</p> <p>R02_MOVEDADD01 R02_MOVEDADD02 R02_MOVEDADD03 R02_MOVEDADD04 R02_MOVEDADD05 R02_MOVEDADD06 R02_MOVEDADD07</p>	

NAVIGATION: Go to Box 5.

PATH ID: R02_VTA14	Screen ID:						
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>YOU'VE INDICATED THAT {NAME} IS DECEASED.</p> <p>PRESS 1 TO CONFIRM.</p> <p>PRESS 7 TO GO BACK.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; text-align: center;">1</td> <td style="width: 33%; text-align: center;">CONFIRM</td> <td style="width: 33%; text-align: center;">GO TO R02_VTA15</td> </tr> <tr> <td style="text-align: center;">7</td> <td style="text-align: center;">GO BACK</td> <td style="text-align: center;">GO TO R02_VTA10</td> </tr> </table> <p>ASK: If R02_VTA10 = 7.</p>		1	CONFIRM	GO TO R02_VTA15	7	GO BACK	GO TO R02_VTA10
1	CONFIRM	GO TO R02_VTA15					
7	GO BACK	GO TO R02_VTA10					

PATH ID: R02_VTA15	Screen ID:			
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>I am very sorry to hear of your loss. I will update my records and will make sure we don't follow-up about {NAME} again.</p> <p>PRESS 1 TO CONTINUE.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; text-align: center;">1</td> <td style="width: 33%; text-align: center;">CONTINUE</td> <td style="width: 33%; text-align: center;">GO TO BOX 7</td> </tr> </table> <p>ASK: Ask in all instances when the VT Respondent reports the SP to have deceased.</p> <p>PROGRAM: If Response = 1, set Adult SP (Task 211/212) or Youth SP (Task 230/231) to Deceased, then continue to Box 7.</p>		1	CONTINUE	GO TO BOX 7
1	CONTINUE	GO TO BOX 7		

PATH ID: R02_VTA16	Screen ID:						
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>YOU'VE INDICATED THAT {NAME} DID NOT PERMANENTLY MOVE BUT IS TEMPORARILY AWAY FROM {PROGRAM: INSERT W2_LINKED_ADDRESS} FOR ANOTHER REASON.</p> <p>PRESS 1 TO CONFIRM.</p> <p>PRESS 7 TO GO BACK.</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%; text-align: center;">1</td> <td style="width: 33%; text-align: center;">CONFIRM</td> <td style="width: 33%; text-align: center;">GO TO R02_VTA17</td> </tr> <tr> <td style="text-align: center;">7</td> <td style="text-align: center;">GO BACK</td> <td style="text-align: center;">GO TO R02_VTA10</td> </tr> </table> <p>ASK: Ask in all instances when the VT Respondent reports the SP is no longer at the W2_LINKED_ADDRESS for another reason (besides having permanently moved).</p> <p>PROGRAM: If Response = 1, set Adult SP (Task 211/212) or Youth SP (Task 230/231) to Temporarily Away (IAW).</p>		1	CONFIRM	GO TO R02_VTA17	7	GO BACK	GO TO R02_VTA10
1	CONFIRM	GO TO R02_VTA17					
7	GO BACK	GO TO R02_VTA10					

PATH ID: R02_VTA17	Screen ID:
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>Can you provide any information about where {{NAME} is/you are} currently?</p> <p>PROBE TO OBTAIN THE FOLLOWING INFORMATION:</p> <ul style="list-style-type: none"> • TYPE OF PLACE AND ADDRESS WHERE SP CURRENTLY RESIDES. • PHONE NUMBER, IF APPLICABLE. • EXPECTED RETURN DATE/LENGTH OF TIME AWAY FROM HOUSEHOLD. • IF RESPONDENT VOLUNTEERS, NOTE IF SP HAS PHYSICAL/MENTAL IMPAIRMENT... <p>ASK: If R02_VTA16 = 1.</p> <p>NAVIGATION: GO TO BOX 5.</p>	
<p>BOX 5</p> <p>If SP=W2_ADULT (or) SP=VT R + SP = W2_EXPECTEDADULT) + (R02_AddressType = NewVerify) + (AgeAtBaseline = 17), go to Box 6C. Else if (SP=W2_EXPECTED ADULT) or (SP = W2_YOUTH + R02_CURRENT_AGE_LD >=18), go to R02_VTA20. Else if SP=W2_YOUTH, go to Box 6A.</p> <p>PROGRAM – Exception: If R02_AddressType = R02_NewVerify, change any W2_EXPECTEDADULT confirmed as 18+ in previous VT to W2 Expected Event Type = W2_ADULT, and go to Box 6C.</p>	

PATH ID: R02_VTA20	Screen ID:									
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>Our records indicate that {NAME} is now 18 or older. Is this correct?</p> <table style="width: 100%; margin-top: 10px;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 60%;">YES, SP IS 18 OR OLDER</td> <td style="width: 30%;">GO TO BOX 5A</td> </tr> <tr> <td style="text-align: center;">2</td> <td>NO, SP IS 17 OR YOUNGER</td> <td>GO TO BOX 5B</td> </tr> <tr> <td style="text-align: center;">9</td> <td>DON'TKNOW/REFUSE</td> <td>GO TO BOX 6A</td> </tr> </table> <p>ASK: If SP = R02_W2_EXPECTED ADULT. (Routing from Box 3 or Box 5.)</p>		1	YES, SP IS 18 OR OLDER	GO TO BOX 5A	2	NO, SP IS 17 OR YOUNGER	GO TO BOX 5B	9	DON'TKNOW/REFUSE	GO TO BOX 6A
1	YES, SP IS 18 OR OLDER	GO TO BOX 5A								
2	NO, SP IS 17 OR YOUNGER	GO TO BOX 5B								
9	DON'TKNOW/REFUSE	GO TO BOX 6A								

BOX 5A

DISPLAY HARD ERROR:

YOU HAVE INDICATED THE BASELINE YOUTH SP IS NOW 18 YEARS OF AGE, AND IS NOW AN ADULT.

PRESS S IF YES.

PRESS G TO GO BACK AND EDIT ENTRY.

S SUPPRESS
G GO BACK

GO TO R02_VTA25
GO TO R02_VTA20

BOX 5B

DISPLAY HARD ERROR:

YOU HAVE INDICATED THE BASELINE YOUTH SP IS STILL 17 YEARS OF AGE OR YOUNGER, AND IS STILL A YOUTH.

PRESS S IF YES.

PRESS G TO GO BACK AND EDIT ENTRY.

S SUPPRESS
G GO BACK

GO TO BOX 6A
GO TO R02_VTA20

PATH ID: R02_VTA25

Screen ID:

DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER

{We would like to get in touch with {NAME} to discuss the next steps in the PATH Study.} What is the best phone number to reach {NAME}?

(Since {NAME} is now 18, for purposes of this study {he/she} is considered an adult.)

____ PHONE NUMBER ENTRY FIELD

GO TO BOX 7

ASK: If R02_VTA20 = 1.

Program: Display SP name in {NAME}.

PATH ID: BOX 6A

Screen ID:

Routing Description: If the W1 Parent is not already confirmed as NOT living at the W2_LINKED_ADDRESS, go to VTA26 (which asks if the W1 Parent is still the best parent to contact). [Assume the Parent is still at this address, until we know otherwise.] If the W1 Parent has been confirmed as NOT living at the W2_LINKED_ADDRESS, go to VTA27.

PATH ID: R02_VTA26	Screen ID:						
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>Last time we visited your household, we spoke with {BASELINE PARENT NAME/you} about {YOUTH NAME}. {Is this/Are you} still the best person to contact regarding {YOUTH NAME}'s participation in the PATH Study?</p> <p>THE PARENT MUST LIVE WITH {YOUTH/SHADOW YOUTH NAME}.</p> <p>REMINDER: A PARENT OR GUARDIAN CAN BE A ROLE, RATHER THAN A RELATIONSHIP. THE PARENT OR GUARDIAN MUST LIVE WITH THE CHILD, SHOULD BE KNOWLEDGEABLE ABOUT THE YOUTH AND BE RESPONSIBLE FOR MAKING DECISIONS ON YOUTH'S ACTIVITIES, LIKE SCHOOL PERMISSIONS, WHERE TO LIVE, ETC.</p> <table style="width: 100%; margin-top: 20px;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 50%;">YES</td> <td style="width: 40%; text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">2</td> <td>NO</td> <td style="text-align: right;">GO TO R02_VTA27</td> </tr> </table> <p>ASK: Ask when SP = W2_YOUTH and the Parent & Youth have been confirmed as living at the W2_LINKED_ADDRESS. Route to VTA26 also in instances when the VT R = W1 Parent even if the W1 Parent is not an SP.</p>		1	YES	GO TO BOX 6B	2	NO	GO TO R02_VTA27
1	YES	GO TO BOX 6B					
2	NO	GO TO R02_VTA27					

PATH ID: R02_VTA27	Screen ID:																																	
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>Who would be the best person to contact regarding {NAME}'s continued participation in the PATH Study?</p> <p>THE PARENT MUST LIVE WITH {YOUTH/SHADOW YOUTH NAME}.</p> <p>REMINDER: A PARENT OR GUARDIAN CAN BE A ROLE, RATHER THAN A RELATIONSHIP. THE PARENT OR GUARDIAN MUST LIVE WITH THE CHILD AND SHOULD BE KNOWLEDGEABLE ABOUT THE YOUTH AND BE RESPONSIBLE FOR MAKING DECISIONS ON YOUTH'S ACTIVITIES, LIKE SCHOOL PERMISSIONS, WHERE TO LIVE, ETC.</p> <table style="width: 100%; margin-top: 20px;"> <tr> <td style="width: 10%; text-align: center;">1</td> <td style="width: 50%;">NAME/AGE/GENDER</td> <td style="width: 40%; text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">2</td> <td>NAME/AGE/GENDER</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">3</td> <td>NAME/AGE/GENDER</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">4</td> <td>NAME/AGE/GENDER</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">5</td> <td>NAME/AGE/GENDER</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">6</td> <td>NAME/AGE/GENDER</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">7</td> <td>NAME/AGE/GENDER</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">8</td> <td>NAME/AGE/GENDER</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">9</td> <td>(NAME OF VT R)</td> <td style="text-align: right;">GO TO BOX 6B</td> </tr> <tr> <td style="text-align: center;">98</td> <td>NO PARENT LIVES WITH YOUTH</td> <td style="text-align: right;">GO TO R02_VTA29B</td> </tr> <tr> <td style="text-align: center;">99</td> <td>NEW PARENT IDENTIFIED</td> <td style="text-align: right;">GO TO R02_VTA28</td> </tr> </table> <p>ASK: Ask of W2_YOUTH or W2_EXPECTED ADULTS confirmed to still be 17 and for which the W1 Parent is not the best person to contact regarding the youth's continued participation in the study.</p>		1	NAME/AGE/GENDER	GO TO BOX 6B	2	NAME/AGE/GENDER	GO TO BOX 6B	3	NAME/AGE/GENDER	GO TO BOX 6B	4	NAME/AGE/GENDER	GO TO BOX 6B	5	NAME/AGE/GENDER	GO TO BOX 6B	6	NAME/AGE/GENDER	GO TO BOX 6B	7	NAME/AGE/GENDER	GO TO BOX 6B	8	NAME/AGE/GENDER	GO TO BOX 6B	9	(NAME OF VT R)	GO TO BOX 6B	98	NO PARENT LIVES WITH YOUTH	GO TO R02_VTA29B	99	NEW PARENT IDENTIFIED	GO TO R02_VTA28
1	NAME/AGE/GENDER	GO TO BOX 6B																																
2	NAME/AGE/GENDER	GO TO BOX 6B																																
3	NAME/AGE/GENDER	GO TO BOX 6B																																
4	NAME/AGE/GENDER	GO TO BOX 6B																																
5	NAME/AGE/GENDER	GO TO BOX 6B																																
6	NAME/AGE/GENDER	GO TO BOX 6B																																
7	NAME/AGE/GENDER	GO TO BOX 6B																																
8	NAME/AGE/GENDER	GO TO BOX 6B																																
9	(NAME OF VT R)	GO TO BOX 6B																																
98	NO PARENT LIVES WITH YOUTH	GO TO R02_VTA29B																																
99	NEW PARENT IDENTIFIED	GO TO R02_VTA28																																

PATH ID: R02_VTA28	Screen ID:
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>ENTER FIRST AND LAST NAME OF NEW PARENT.</p> <p>____ NAME ENTRY FIELDS GO TO R02_VTA29</p> <p>ASK: Collect new Parent first and last name in instances when option of 'New Parent Identified' is selected in R02_VTA27.</p>	

PATH ID: R02_VTA29	Screen ID:
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>What is their telephone number?</p> <p>____ TELEPHONE ENTRY FIELDS GO TO BOX 6AA</p> <p>ASK: Collect new Parent phone number in instances when option of 'New Parent Identified' is selected in R02_VTA27.</p>	

PATH ID: R02_VTA29B	Screen ID:
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>DOCUMENT ANY INFORMATION PROVIDED ABOUT SITUATION WHEN NO HOUSEHOLD MEMBER FILLS PARENT ROLE.</p> <p>ASK: Collect clarifying information in instances when there is no one that fits the Parent role in the household.</p> <p>NAVIGATION: GO TO BOX 7.</p>	

<p>BOX 6AA</p> <p>(From R02_VTA29):</p> <p>If original VT results in a split so this VT is R02_AddressType = R02_NewVerify and parent name response option selected in this VT at R02_VTA27 Parent is a new parent identified from a previous VT, go to Box 6B.</p> <p>Else, If New Parent identified in R02_VTA27 and named in R02_VTA28 is not yet assigned a respondent PID, set flag NewPersoninVT = 1 and set R02_PersonType =New Parent.</p> <p>NAVIGATION: Go to Box 6B</p>
--

BOX 6B

Routing: If the SP row/instance's phone number was previously obtained, e.g. the unique person's telephone number was asked already b/c the person is an also an Adult SP or a Parent of another Y/SY, go to Box 7. If the parent selected in VTA27 is also the VT R: R02_VTA01 = 9, R name provided in R02_VTA01B, and phone number obtained in R02_VTA01C, go to Box 7. Else, go to Box 6C.

BOX 6C

If SP row/instance is for the VT R and we have a phone number, go to R02_VTA30. If SP row/instance is for the VT R and we do not have a phone number, go to R02_VTA35. If SP row/instance is not the VT R and we have a phone number, go to R02_VTA40. If SP row/instance is not the VT R and we do not have a phone number, go to R02_VTA40B.

PATH ID: R02_VTA30

Screen ID:

DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER

I have your best phone number as {(XXX) XXX-XXXX}. Is that correct?

- 1 YES
- 2 NO

GO TO BOX 7

GO TO R02_VTA35

ASK: Best phone number confirmation question asked of VT R. (Only asked if the VT Respondent = Adult SP (or) Parent.) Only asked if the VT Respondent has a phone number on record.

PATH ID: R02_VTA35

Screen ID:

DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER

What is the best telephone number to reach you?

ENTER THE NUMBERS ONLY. DO NOT ENTER HYPHENS OR OTHER SYMBOLS.

DISPLAY TELEPHONE NUMBER FIELDS.

ASK: VT Respondent who needs to correct/update their best phone number, or do not have any phone numbers (routing would have skipped R02_VTA30).

NAVIGATION: GO TO BOX 7.

PATH ID: R02_VTA40	Screen ID:															
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>(We would like to contact {ADULT NAME/PARENT NAME/you} to schedule an appointment for an interview {about {YOUTH NAME}}.)</p> <p>[I have the following phone numbers for {ADULT NAME/PARENT NAME/you}.] Which is the best number?</p> <p>READ PHONE NUMBERS BELOW, STOPPING ONCE RESPONDENT IDENTIFIES BEST NUMBER. SELECT 4 to ENTER NEW PHONE NUMBER.</p> <table style="margin-left: 40px; border: none;"> <tr> <td style="width: 5%;">1</td> <td style="width: 60%;">PHONE NUMBER</td> <td style="width: 35%;">GO TO BOX 7</td> </tr> <tr> <td>2</td> <td>PHONE NUMBER</td> <td>GO TO BOX 7</td> </tr> <tr> <td>3</td> <td>PHONE NUMBER</td> <td>GO TO BOX 7</td> </tr> <tr> <td>4</td> <td>ENTER NEW PHONE NUMBER</td> <td>GO TO R02_VTA40B</td> </tr> <tr> <td>9</td> <td>REFUSED / DO NOT CONTACT</td> <td>GO TO BOX 7</td> </tr> </table> <p>ASK: Ask of row instances of Adult or Youth who are not the VT Respondent and for who best contact phone number has not previously been obtained (not previously obtained in any prior loop in this instrument).</p> <p>NAVIGATION: Go to Box 7 (End of Loop).</p>		1	PHONE NUMBER	GO TO BOX 7	2	PHONE NUMBER	GO TO BOX 7	3	PHONE NUMBER	GO TO BOX 7	4	ENTER NEW PHONE NUMBER	GO TO R02_VTA40B	9	REFUSED / DO NOT CONTACT	GO TO BOX 7
1	PHONE NUMBER	GO TO BOX 7														
2	PHONE NUMBER	GO TO BOX 7														
3	PHONE NUMBER	GO TO BOX 7														
4	ENTER NEW PHONE NUMBER	GO TO R02_VTA40B														
9	REFUSED / DO NOT CONTACT	GO TO BOX 7														

PATH ID: R02_VTA40B	Screen ID:
<p>DISPLAY: {ADULT/YOUTH/SHADOW YOUTH} NAME/AGE/GENDER</p> <p>[We would like to contact {ADULT NAME/PARENT NAME} to schedule an appointment for an interview {about {YOUTH NAME}}].</p> <p>What is the best number?</p> <p>DISPLAY TELEPHONE NUMBER FIELD.</p> <p>ASK: NON VT Respondent who has new phone number or does not have any phone numbers (routing would have skipped R02_VTA40).</p> <p>NAVIGATION: GO TO BOX 7.</p>	
<p>BOX 7 – END OF LOOP</p> <p>If data has been collected for each SP row instance, N, and updated address information was received for any SP row instance, go to R02_VTA50. Else if data has been collected for each SP row instance N and no updated address information has been received, go to R02_VTA55.</p> <p>Else, go to R02_VTA05 for row instance (N+1).</p>	

PATH ID: R02_VTA50

Screen ID:

Before we end, I'd like to summarize some of the updated address information you told me today. I recorded that:

SP Name	New Address Information

ASK: Summary page with data that should be confirmed for each SP, only in instances when new address information was obtained in R02_VTA12 (or) R02_VTA13, or other known information was obtained in R02_VTA17.

If new address info was obtained for some but not all SPs, display only those SPs for which updated address information/known information was obtained in R02_VTA10X/R02_VTA12 (or) R02_VTA13 (or) R02_VTA17.

Else, skip R02_VTA50 and go to R02_VTA55..

1	CONFIRM	GO TO BOX 9
7	EDIT	GO TO BOX 8

PROGRAM: Confirm each person's info one (row) at a time at the very end of the instrument (after the end of all SP Loops.)

PROGRAM: Loop through and display information for each row, user must select 1 = Confirm or 7 = Edit for each SP row instance in the table. If User selects option to edit, go to Box 8.

BOX 8

If R02_VTA50 = 7 for said SP instance, display the following logic check table – hard error:

SELECT ANY ROW FROM THE LIST BELOW TO GO BACK AND EDIT THAT ITEM.

UPDATE INFORMATION WHERE NEEDED:

SP Name (Disable/disallow any edit name functionality)

New Address Information (Able to Edit and go to R02_VTA05 (or) R02_VTA10 (or) R02_VTA12/13 (or) R02_VTA17.

PROGRAM: Display Box 8 with one SP's data at a time and only if R02_VTA50 = 7 for said SP. Allow user to select row, then click to change the response given to one or more fields for the associated SP row instance.

PROGRAM: If any one value in any SP instance row is changed, always redisplay R02_VTA50 for the associated SP. Allow for multiple loops to edit the fields. R02_VTA50 must be confirmed (response option = 1) for each SP instance for which there is new address information before continuing.

BOX 9

Once data has been confirmed for each SP instance for which updated address information was obtained, go to R02_VTA55, Else, return to R02_VTA50 for row instance (N+1).

PATH ID: R02_VTA55

Screen ID:

{TRY TO SCHEDULE ANY SP APPOINTMENTS, AND THEN DOCUMENT THE APPOINTMENT IN AN EROC. TRY TO TRANSITION DIRECTLY TO SP LEVEL DATA COLLECTION TASKS. }

PRESS 1 TO RETURN TO IMS.

1 EXIT

GO TO END

ASK: When Loop for each SP instance has been completed (or) all fields for all SPs in R02_VTA50 have been confirmed.

PROGRAM: If R02_VTA00 = 1, DISPLAY "TRY TO SCHEDULE ANY SP APPOINTMENTS, AND THEN DOCUMENT THE APPOINTMENT IN AN EROC." If R02_VTA00 = 7, DISPLAY "TRY TO TRANSITION DIRECTLY TO SP LEVEL DATA COLLECTION TASKS. "

END

0925-0664

OMB Control Number:

Expiration Date: XX/XX/XXXX

Attachment C PATH Study Validation Form

Intro_A.

Hello, my name is <VALIDATOR'S NAME> and I am calling on behalf of the Population Assessment of Tobacco and Health (PATH) Study. May I please speak with < SP NAME>?

- (IF YOU ARE SPEAKING WITH THE SP....CONTINUE TO Q1)
- (IF SP IS CALLED TO THE PHONE....INTRODUCE YOURSELF AGAIN AND CONTINUE TO Q1)
 - (IF SP IS NOT AVAILABLE....GO TO END_B)
 - (IF NO SUCH PERSON AT PHONE NUMBER....GO TO END_A)

1. Just to confirm, am I speaking with < NAME>?

- YES 1 (GO TO Q2)
- NO 2 (GO TO END_B)

2. Recently one of our interviewers visited your address to conduct an interview as part of the Population Assessment of Tobacco and Health (PATH) Study. Do you remember talking to him or her?

- YES 1 (SKIP TO Q7)
- NO 2 (GO TO Q3)

3. During the interview, you were asked questions about your health and tobacco use. Do you remember the visit now?

- YES 1 (SKIP TO Q7)
- NO 2 (GO TO Q4)

Public reporting burden for this collection of information is estimated to average 4 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 (0925-0664). Do not return the completed form to this address.

4. On **<WAVE 2 ADULT INTERVIEW>** did you live at **<ADDRESS>**?

YES 1 (SKIP TO Q6)

NO 2 (GO TO Q5)

5. When did you move to this address?

_____ (GO TO END_D)

6. Perhaps there is a mistake. I'd like to make sure that I dialed correctly. Is this **<PHONE NUMBER>**?

YES 1 (GO TO END_D)

NO 2 (GO TO END_A)

7. On all of our studies, we routinely re-contact some people who were interviewed to make sure our interviewers are following procedures correctly. My questions today will take only a few minutes. Is this a good time for you?

YES 1 (GO TO Q8)

NO 2 (GO TO END_C)

8. Please know that information from our call today will be kept private and used only for the PATH Study.

(CONTINUE TO Q9)

9. During the visit, was the interviewer polite and courteous?

YES 1 (CONTINUE)

SOMEWHAT 2 (CONTINUE)

NO 3 (CONTINUE)

DON'T RECALL 4 (CONTINUE)

REFUSED 5 (CONTINUE)

On the day of the interview, approximately how long would you say the visit lasted?

LESS THAN 15 MINUTES..... 1 (CONTINUE)

BETWEEN 15 MINUTES TO 30 MINUTES..... 2 (CONTINUE)

BETWEEN 31 MINUTES TO 60 MINUTES..... 3 (CONTINUE)

LONGER THAN ONE HOUR..... 4 (CONTINUE)

DON'T RECALL..... 5 (CONTINUE)

REFUSED..... 6 (CONTINUE)

10. Did the interviewer give you a copy of our consent document to read? This was a document that included information about the PATH Study and discussed your consent to participate in an interview.

- YES 1 (CONTINUE)
- NO 2 (CONTINUE)
- DON'T RECALL..... 3 (CONTINUE)
- REFUSED.....4 (CONTINUE)

11. For part of the visit, did the interviewer turn the laptop towards you and ask you to read the questions to yourself and enter your answers directly into the laptop?

- YES 1 (CONTINUE)
- NO 2 (CONTINUE)
- DON'T RECALL..... 3 (CONTINUE)
- REFUSED..... 4 (CONTINUE)

12. Did the interviewer give you a new debit card or tell you that a new payment will be added to your existing PATH debit card to thank you for your participation?

- YES..... 1 (CONTINUE)
- NO 2 (CONTINUE)
- DON'T RECALL..... 3 (CONTINUE)
- REFUSED..... 4 (CONTINUE)

13. During the most recent visit, did the interviewer ask for your permission to collect a urine sample?

- YES 1 (CONTINUE)
- NO 2 (CONTINUE)
- DON'T RECALL..... 3 (CONTINUE)
- REFUSED..... 4 (CONTINUE)

14. Did you give a urine sample?

- YES 1 (CONTINUE)
- NO 2 (CONTINUE)
- DON'T RECALL..... 3 (CONTINUE)
- REFUSED..... 4 (CONTINUE)

15. During the most recent visit, did the interviewer ask for your permission to let a health professional visit to collect blood?

- YES..... 1 (CONTINUE TO BOX A)
- NO.....2 (CONTINUE TO BOX A)
- DON'T RECALL.....3 (CONTINUE TO BOX A)
- REFUSED.....4 (CONTINUE TO BOX A)

Box A
Routing Instructions:
IF Blood Collection visit was completed, GO TO Q17.
OTHERWISE, SKIP TO Q18.

16. During the visit by the health professional who collected the blood sample, was the health professional polite and courteous?

- YES1 (CONTINUE)
- SOMEWHAT.....2 (CONTINUE)
- NO3 (CONTINUE)
- BLOOD DRAW NOT TAKEN.....4 (CONTINUE)
- DON'T RECALL.....5 (CONTINUE)
- REFUSED.....6 (CONTINUE)

17. Would you like to tell me anything else about the interviewer?

_____ (CONTINUE)

18. What is your current address?

_[ADDRESS 1]_____

_[ADDRESS 2]_____

_[CITY/STATE/ZIP]_____ (CONTINUE)

- REFUSED..... 2 (GO TO END_E)

19. VALIDATOR INSTRUCTIONS. DO NOT READ TO RESPONDENT.

WAS THE ADDRESS PROVIDED ON THE PREVIOUS QUESTION THE SAME ADDRESS AS BELOW? CODE AS "YES" IF ADDRESS IS SIMILAR. DOES NOT HAVE TO BE AN EXACT MATCH.

<ADDRESS>_____

- YES..... 1 (GO TO END_E)
- NO..... 2 (CONTINUE TO Q21)
- NOT SURE 3 (CONTINUE TO Q21)

20. Did the interviewer visit you at this address to conduct the interview?

- YES..... 1 (GO TO END_F)
- NO..... 2 (CONTINUE TO Q22)
- DON'T RECALL..... 3 (GO TO END_F)
- REFUSED..... 4 (GO TO END_F)

21. At what address did the interviewer visit you to conduct the interview?

_[ADDRESS 1]_____

_[ADDRESS 2]_____

_[CITY/STATE/ZIP]_____ (CONTINUE TO Q23)

- REFUSED..... 2 (GO TO END_F)

22. VALIDATOR INSTRUCTIONS. DO NOT READ TO RESPONDENT.

WAS THE ADDRESS PROVIDED ON THE PREVIOUS QUESTION THE SAME ADDRESS AS BELOW? CODE AS "YES" IF ADDRESS IS SIMILAR. DOES NOT HAVE TO BE AN EXACT MATCH.

<ADDRESS>_____

- YES..... 1 (GO TO END_E)
- NO..... 2 (GO TO END_F)
- NOT SURE 3 (GO TO END_E)

- IF QUESTIONS ARE ASKED, PLEASE REFER SP TO THE PATH SUPPORT DESK AT 1-888-311-1819.
- GO TO END_E

END_A: I apologize. I have the wrong number. Thank you. Goodbye.

END_B: Thank you for your time. What is a good day and time to reach < SP NAME>? What phone number is best to use?

DATE: _____

TIME: _____ am pm

PHONE NUMBER: _____

REFUSED FURTHER CONTACT

Thank you. Goodbye.

END_C: What is a good day and time to reach you again?

DATE: _____

TIME: _____ am pm

PHONE NUMBER: _____

REFUSED FURTHER CONTACT

Thank you. Goodbye.

END_D: Thank you for your time. There seems to be a problem with some of our information. I will check our records and someone may call you back.

Thank you. Goodbye.

END_E: Those are all the questions I have. Thank you so much for your time today. Goodbye.

END_F: Those are all the questions I have. Thank you so much for your time today. Goodbye.

PROGRAMMER NOTE: SET RESULT CODE TO VR (Validation Risk)

[PLEASE READ THE FOLLOWING MESSAGE INTO THE ANSWERING MACHINE.]

Hello, I'm calling on behalf of the Population Assessment of Tobacco and Health Study, PATH. We'd like a few minutes of <FNAME> <LNAME>'s time to verify some information (he/she) provided. We will call back another time or you may call us at 1-877-709-5807.

Attachment D

Table A-3. **Corrected PATH Study Wave 2 hour burden estimates**

Type of respondent and instrument	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults - Baseline adult respondents -Extended Interview	27,795	1	1	27,795
Adults - Baseline youth respondents who age into adult cohort - Consent for Extended Interview	2,090	1	4/60	139
Adults - Baseline youth respondents who age into adult cohort - Extended Interview	1,812	1	68/60	2,054
Adults - Baseline youth respondents who age into the adult cohort -- Consent for Biological Samples	1,812	1	5/60	151
Adults - Biospecimen Collection: Urine	12,909	1	10/60	2,152
Adults - Biospecimen Collection: Blood	1,041	1	18/60	312
Adults - Tobacco Use Form	13,950	1	4/60	930
Adults - Follow-up/Tracking Participant Information Form	34,070	2	8/60	9,085
Youth - Extended Interview	10,048	1	32/60	5,359
Youth - Shadow youth who age into youth cohort -- Assent for Extended Interview	2,229	1	3/60	111
Youth - Shadow youth who age into youth cohort - Extended Interview	2,007	1	42/60	1,405
Adult - Parent Interview	10,249	1	14/60	2,391
Adults - Parents of Shadow youth who age into youth cohort - Parent Permission and Consent for Parent Interview	2,229	1	5/60	186
Adults - Parents of Shadow youth who age into youth cohort -- Parent Interview	2,047	1	17/60	580
Adults -- Verification Call	34,528	1	2/60	1,151
Adults -- Validation Call	3,891	1	4/60	259
Adults - Follow-up/Tracking Participant Information Form for Youth (completed by parents)	2,047	1	17/60	580
Adults - Follow-up/Tracking Participant Information Form for	13,836	2	8/60	3,690

sample Shadow youth (completed by parents)				
Adults - Follow-up/Tracking Participant Information Form for sample Shadow youth (completed by parents)	4,772	2	8/60	1,273
Total				59,023

* Estimated total number of adult extended interview respondents is 27,795 + 1,812 = 29,607.

** Estimated total number of youth extended interview respondents is 10,048 + 2,007 = 12,055.

Attachment E

Table A-4. **Corrected PATH Study Wave 2 annualized cost to respondents**

Type of respondent and instrument	Number of respondents	Frequency of response	Average time per respondent	Annual hour burden	Hourly wage rate	Respondent Cost
Adults - Baseline adult respondents - Extended Interview	27,795	1	1	27,795	\$16.87	\$468,902
Adults - Baseline youth respondents who age into adult cohort - Consent for Extended Interview	2,090	1	4/60	139	\$16.87	\$2,345
Adults - Baseline youth respondents who age into the adult cohort -- Extended interview	1,812	1	68/60	2,054	\$16.87	\$34,651
Adults - Baseline youth respondents who age into the adult cohort -- Consent for Biological Samples	1,812	1	5/60	151	\$16.87	\$2,547
Adults - Biospecimen Collection: Urine	12,909	1	10/60	2,152	\$16.87	\$36,304
Adults - Biospecimen Collection: Blood	1,041	1	18/60	312	\$16.87	\$5,263
Adults - Tobacco Use Form	13,950	1	4/60	930	\$16.87	\$15,689
Adults - Follow-up/Tracking Participant Information Form	34,070	2	8/60	9,085	\$16.87	\$153,264
Youth - Extended Interview	10,048	1	32/60	5,359	\$7.25	\$38,853
Youth - Shadow youth who age into youth cohort -- Assent for Extended Interview	2,229	1	3/60	111	\$7.25	\$805
Youth - Shadow youth who age into youth cohort--youth Interview	2,007	1	42/60	1,405	\$7.25	\$10,186
Adult - Parent Interview	10,249	1	14/60	2,391	\$16.87	\$40,336

Adults - Parents of Shadow youth who age into youth cohort - Parent Permission and Consent for Parent Interview	2,229	1	5/60	186	\$16.87	\$3,138
Adults - Parents of Shadow youth who age into youth cohort - Parent Interview	2,047	1	17/60	580	\$16.87	\$9,785
Adults -- Verification Interview	34,528	1	2/60	1,151	\$16.87	\$19,417
Adults -- Validation Interview	3,891	1	4/60	259	\$16.87	\$4,369
Adults - Follow-up/Tracking Participant Information Form for Youth (completed by parents)	13,836	2	8/60	3,690	\$16.87	\$62,250
Adults - Follow-up/Tracking Participant Information Form for sample Shadow youth (completed by parents)	4,772	2	8/60	1,273	\$16.87	\$21,476
Total						\$929,580

* Estimated total number of adult extended interview respondents is 27,795 + 1,812 = 29,607.

** Estimated total number of youth extended interview respondents is 10,048 + 2,007 = 12,055.