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| **About the Measure** | |
| **Protocol Id** | 730401 |
| **Domain:** | Tobacco Regulatory Research: Agent |
| **Measure:** | Passive Exposures to Tobacco Products |
| **Definition:** | Instrument used to assess a respondent’s exposure to smoke or exhaled electronic cigarette vapor/aerosol in different environments, including work, home, and social settings. |
| **Purpose:** | This measure is necessary in estimating the physicochemical environmental exposures from tobacco products encountered by respondents and the population as a whole including users and nonusers of tobacco. |
| **Essential PhenX Protocols:** | Passive Smoke Exposure [70301] |
| **Related PhenX Protocols:** | Current Environmental Tobacco Smoke Exposure [60701] Self-reported Exposure to Tobacco Product Advertisements [740601] |
| **Measure Release Date:** | June 24, 2015 |

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| **About the Protocol** | |
| **Protocol Release Date:** | June 24, 2015 |
| **Protocol Review Date:** | June 24, 2015 |
| **PhenX Protocol Name:** | Passive Exposures to Tobacco Products |
| **Protocol Name From Source:** | National Adult Tobacco Survey (NATS), 2009 and the Population Assessment of Tobacco and Health (PATH) Survey, 2009-2010 |
| **Protocol Availability:** | Available |
| **Keywords:** | Tobacco Regulatory Research; TRR; agent; passive exposures; passive exposures to tobacco products; smoke indoors; tobacco product use; environmental tobacco smoke exposure; passive smoke exposure; secondhand smoke exposure; secondhand smoke; second-hand smoke; passive vaping |
| **Description:** | This protocol includes the National Adult Tobacco Survey (NATS) and the Population Assessment of Tobacco and Health (PATH) Survey. Collectively, the questions are used to assess a respondent’s exposure to smoke in different environments. |
| **Specific Instructions:** | For these protocols, "smoking" and/or "smoke tobacco" and/or "used tobacco" includes the following acts: smoking tobacco products that are burned (e.g., combustible cigarette, little cigar, cigarillo, and hookah/water pipe); but does NOT include vaping an electronic cigarette. In the **Secondhand Smoke Exposure Section** of the protocol, questions 17 & 19, vaping and electronic cigarette use is addressed by specifying it as a separate category of tobacco product.  In order to fully capture this measure, the Agent WG recommends that investigators also administer the questions from the Passive Smoke Exposure measure currently in the PhenX Toolkit. |
| **Protocol:** | 1. Not counting decks, porches, or garages, during the past 7 days, that is, since last [TODAY’S DAY OF WEEK], on how many days did **someone other than you** smoke tobacco inside your home while you were at home?  [ ] 0\_ NUMBER OF DAYS  [ ] 88 NONE  [ ] 77 DON’T KNOW/NOT SURE  [ ] 99 REFUSED  2. Not counting decks, porches, or garages, inside **your home**, is smoking …?  [ ] 1 **Always** allowed  [ ] 2 Allowed only at **some** times or in **some** places  [ ] 3 **Never** allowed  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  Asked of respondents (who reported that no one else smoked tobacco in their home in the past 7 days and live in homes where smoking is never allowed) or (who reported that someone else smoked tobacco in their home in at least one of the past 7 days and live in homes where smoking is allowed at some times or in some places).  3. Not counting decks, porches, or garages, to your knowledge, during the past 7 days, that is, since last [TODAY’S DAY OF WEEK], has anyone, including yourself, smoked tobacco inside your home when he or she was not supposed to?  [ ] 1 YES  [ ] 2 NO  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  Now I am going to ask you about some questions about policies on tobacco use in the place where you work. But first, I need to know about your employment status.  4. Do you currently have one job or more than one job?  [ ] 1 ONE JOB  [ ] 2 MORE THAN ONE JOB  [ ] 7 DON’T KNOW  [ ] 9 REFUSED  Please answer the following questions for the job at which you spend the most time.  5. Most of the time, do you work…?  [ ] 01 Outdoors  [ ] 02 In a vehicle  [ ] 03 Indoors at home  [ ] 04 Indoors in a place like an office building, retail store, restaurant, or factory  [ ] 96 Somewhere else (Specify)  [ ] 77 DON’T KNOW/NOT SURE  [ ] 99 REFUSED  The next two questions refer to smoking in indoor areas. When answering the questions, please count your vehicle as an indoor area.  6. At your workplace, is smoking in **indoor** areas…?  [ ] 1 Always allowed  [ ] 2 Allowed only at some times or in some places  [ ] 3 Never allowed  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  7. At your workplace, is smoking in **outdoor** areas…?  [ ] 1 Always allowed  [ ] 2 Allowed only at some times or in some places  [ ] 3 Never allowed  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  8. At your workplace, is the use of chewing tobacco, snuff, dip, or snus …?  [ ] 1 Always allowed  [ ] 2 Allowed only at some times or in some places  [ ] 3 Never allowed  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  9. To your knowledge, during the past 30 days, that is, since [DATE FILL], has anyone, including yourself, used tobacco products of any kind, including electronic cigarettes, at your work when he or she was not supposed to?  [ ] 1 YES  [ ] 2 NO  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  Now we have two questions about smoking in vehicles.  10. During the past 7 days, that is, since last [TODAY’S DAY OF WEEK], on how many days did you ride in a vehicle where **someone other than you** was smoking tobacco?  [ ] 0\_ NUMBER OF DAYS  [ ] 88 NONE  [ ] 77 DON’T KNOW/NOT SURE  [ ] 99 REFUSED  11. Not counting motorcycles, in the vehicles that you or family members who live with you own or lease, is smoking…  [ ] 1 Always allowed in all vehicles  [ ] 2 Sometimes allowed in at least one vehicle  [ ] 3 Never allowed in any vehicle  [DO NOT READ]  [ ] 8 RESPONDENT’S FAMILY DOES NOT OWN OR LEASE A VEHICLE  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  The next several questions ask about tobacco use in indoor and outdoor public places. Examples of indoor public places are the indoor areas of stores, restaurants, bars, casinos, clubs, and sports arenas. Examples of outdoor public places are stadiums and parks.  12. Not counting times while you were at work, during the past 7 days, that is, since last [TODAY’S DAY OF WEEK], on how many days did you breathe the smoke from **someone else** who was smoking in an indoor or outdoor public place?  [ ] 0\_ NUMBER OF DAYS  [ ] 88 NONE  [ ] 77 DON’T KNOW/NOT SURE  [ ] 99 REFUSED  13. Not counting times while you were at work, to your knowledge, during the past 7 days, that is, since last [TODAY’S DAY OF WEEK], has anyone, including yourself, used tobacco of any kind in an indoor or outdoor public place when he or she was not supposed to?  [ ] 1 YES  [ ] 2 NO  [ ] 7 DON’T KNOW/NOT SURE  [ ] 9 REFUSED  **Secondhand Smoke Exposure Section**  The next questions ask about tobacco use at your workplace and your home.  14. Which best describes your current job or paid employment status?   |  |  | | --- | --- | | [ ] 1 | Work full-time at least 35 hours per week | | [ ] 2 | Work part-time 15 to 34 hours per week | | [ ] 3 | Work part-time less than 15 hours per week | | [ ] 4 | I don’t currently work for pay | | [ ] -8 | DON’T KNOW | | [ ] -7 | REFUSED |   15. How recently did someone smoke around you while you were at work?  1 [ ] Never  2 [ ] Today  3 [ ] In the past week  4 [ ] In the past two weeks  5 [ ] In the past month  6 [ ] Longer than a month ago but within the past year  7 [ ] More than a year ago  [ ] -8 DON’T KNOW  [ ] -7 REFUSED  16. In your childhood, did you live with a regular smoker who smoked inside your home?  Please think about anyone who smoked cigarettes, cigars, a pipe, or hookah.  1 [ ] Yes  2 [ ] No  [ ] -8 DON’T KNOW  [ ] -7 REFUSED  The next questions ask about the rules of using tobacco inside your home.  17. Does anyone who lives with you now do any of the following? Choose all that apply.  1 [ ] Smoke cigarettes  2 [ ] Use smokeless tobacco, such as chewing tobacco, snuff, dip, or snus  3 [ ] Smoke cigars, cigarillos, or filtered cigars  4 [ ] Use any other form of tobacco, including electronic cigarettes  5 [ ] No one who lives with me now uses any form of tobacco  [ ] -8 DON’T KNOW  [ ] -7 REFUSED  18. During the past seven days, about how many hours were you around others who were smoking, whether or not you were smoking yourself?  Include time in your home, in a car, at school, or outdoors.  1 [ ] I I\_\_I\_\_I  [ ] -8 DON’T KNOW  [ ] -7 REFUSED |
| **Selection Rationale:** | The combination of questions from different questionnaires is necessary because the Population Assessment of Tobacco and Health (PATH) extended interview asks respondents questions about burned (e.g., cigarettes) versus unburned (e.g., electronic cigarette) tobacco products. In addition, these measures have respondents:   * specify the number of days there were exposed to smoke indoors, at work, at home, in transit, and in social settings during the last 7 days; * specify if indoor smoking is allowed and whether they think it should be allowed; and * specify where they work most of the time: outdoors, in a vehicle, indoors at home, indoors in places like an office building or store.   The National Adult Tobacco Survey (NATS) is a validated survey that yields data representative and comparable at both the national and state levels. The PATH Study is a nationally representative, in-person longitudinal cohort study of nonusers and users of tobacco products and those at risk for tobacco use across the United States. Respondents 12 years old and up are asked questions on tobacco use, attitudes, and health, and biospecimens (buccal cell, urine, and blood) are collected from adults. PATH Study data will provide an evidence base for assessing and monitoring FDA’s current and future regulatory actions in meeting its mandate under the Family Smoking Prevention and Tobacco Control Act. Regulatory domains include product standards, new and modified risk products, health warnings, and health education campaigns. |
| **Source:** | Office on Smoking and Health (OSH), National Center for Chronic Disease Promotion and Health Prevention, Centers for Disease Control and Prevention. (2009). Questions 73-75, 77-84, 87, and 90. In *National Adult Tobacco Survey Questionnaire, 2009-2010*. Atlanta, GA: Author.  National Institute on Drug Abuse, National Institutes of Health, Department of Health and Human Services & Food and Drug Administration, Department of Health and Human Services. (2013, June 18). *Population Assessment of Tobacco and Health (PATH), 2013: PATH Adult Extended Questionnaire, Version 7.5* (PATH ID: AM0014, AX0065, AR0144, AX0066, AX0068). Washington, DC: Author. |
| **Language** | English Other languages available at source |
| **Participant:** | Adults (18+) and Youths (12-17) |
| **Personnel and Training Required:** | The interviewer must be trained to conduct personal interviews with individuals from the general population. The interviewer must be trained and found to be competent (i.e., tested by an expert) at the completion of personal interviews. The interviewer should be trained to prompt respondents further if a "don’t know" response is provided. |
| **Equipment Needs:** | None |
| **Standards** |  |
| **General References:** | National Institutes of Health, U.S. Food and Drug Administration. (2013). Population Assessment of Tobacco and Health (PATH) Study: Final Adult Baseline (Wave 1) Questionnaire. Bethesda, MD: National Institutes of Health. |
| **Mode of Administration:** | Interviewer-administered questionnaire |
| **Derived Variables:** | None |
| **Requirements:** | |  |  | | --- | --- | | **Requirement Category** | **Required (Yes/No)** | | **Major equipment** | No | | **Specialized training** | No | | **Specialized requirements for biospecimen collection** | No | | **Average time of greater than 15 minutes in an unaffected individual** | No | |
| **Annotations for Specific Conditions:** | None |
| **Process and Review:** | Not applicable. |