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| **About the Measure** |
| **Protocol Id** | 730901 |
| **Domain:** | Tobacco Regulatory Research: Agent  |
| **Measure:** | Tobacco Warning Label Exposure and Recall  |
| **Definition:** | Questions assessing exposure to health warnings and ability to recall message content.  |
| **Purpose:** | These questions help to assess the effectiveness of health warnings on tobacco packages, which have been associated with perceptions of risk and may promote smoking cessation and reduce uptake among young people.  |
| **Essential PhenX Protocols:** |  |
| **Related PhenX Protocols:** | Tobacco - Smoking Status - Adolescent [30601]Tobacco - Smoking Status - Adult [30602]Cigarette Smoking Status - Adolescent [30603]Cigarette Smoking Status - Adult [30604]Tobacco - Age of Offset of Use - Adolescent [30901]Tobacco - Age of Offset of Cigarette Use - Adult [30902]Tobacco - Age of Offset of Cigarette Use - Adolescent [30903]Smoking Quit Attempts [71001]  |
| **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:** | Tobacco Warning Label Exposure and Recall  |
| **Keywords:** | tobacco warning label exposure and recall; nicotine; agent; Tobacco Regulatory Research; TRR; health warning; health knowledge; Perceived risk; product labeling; Population Assessment of Tobacco and Health; PATH; label; warning; warning label; cigarette; cigarettes; behavior modification  |
| **Description:** | This protocol uses a combination of questions from the Population Assessment of Tobacco and Health (PATH) Study and the 2015 International Tobacco Control (ITC) 4-Country Survey instruments. Collectively, the questions are used to assess the effectiveness of health warnings on tobacco packages, which have been associated with perceptions of risk and may promote smoking cessation and reduce uptake among young people. |
| **Specific Instructions:** | The Population Assessment of Tobacco and Health (PATH) Study is an interviewer-administered survey, but the PhenX Working Group (WG) acknowledges that these questions can also be self-administered. The WG recommends that for questions 2 through 4, the investigator should note the following:* Do not read out list of labels. Select the codes for as many warning labels as respondent is able to describe.
* If respondent does not remember any warning labels, select 9 (Don’t know).

Continue to show prompt until respondent chooses "Don’t know." If response = 8 or 9, end questionnaire. |
| **Protocol:** | 1. In the past 30 days, how often, if at all, have you read or looked closely at the health warnings on cigarette packages?…(1-5 scale, "Never" to "Very often")[ ] 1 Never[ ] 2 Rarely[ ] 3 Sometimes[ ] 4 Often[ ] 5 Very often[ ] -8 DON’T KNOW2. I want you to think about the health warnings that currently appear on the exterior of CIGARETTE PACKS. I’d like you to describe the first warning that comes to mind, if any.**[After first response, prompt:]**3. Please describe the next health warning that comes to mind.**[After second and any subsequent response, prompt:]**4. Do any others come to mind?**[Pre-coded checklist]**SURGEON GENERAL’S WARNING: Cigarette Smoke Contains Carbon Monoxide.[ ] 1 Mentioned[ ] 2 Not mentioned[ ] 7 Not applicable[ ] 8 Refused[ ] 9 Don’t knowSURGEON GENERAL’S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.[ ] 1 Mentioned[ ] 2 Not mentioned[ ] 7 Not applicable[ ] 8 Refused[ ] 9 Don’t knowSURGEON GENERAL’S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy.[ ] 1 Mentioned[ ] 2 Not mentioned[ ] 7 Not applicable[ ] 8 Refused[ ] 9 Don’t know |
| **Selection Rationale:** | The Population Assessment of Tobacco and Health (PATH) Study is a nationally representative, longitudinal cohort study of nonusers and users of tobacco products and of 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. Biospecimens (buccal cell, urine, and blood) are collected from adults. The PATH Study was implemented to provide an evidence base for assessing and monitoring the Food and Drug Administration’s 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.The health warning measures used in PATH are very similar to measures used in other countries, such as the International Tobacco Control (ITC) Survey. The 2015 ITC 4-Country Survey is an international cohort study of tobacco use whose overall objective is to measure the psychosocial and behavioral impact of key national-level policies. This survey is being used in more than 20 countries. |
| **Source:** | Department of Health and Human Services, National Institutes of Health, National Institute on Drug Abuse, Food and Drug Administration. (2013). Population Assessment of Tobacco and Health (PATH). PATH Adult Extended Questionnaire, Version 7.5. (PATH ID: AR0202)International Tobacco Control Policy Evaluation Project. (2015). International Tobacco Control 4-Country Survey 2015, Wave 9, Items 154a, 154b, 154c and 154d. |
| **Language** | EnglishOther languages available at source  |
| **Participant:** | Adults and adolescents 12-17 years old |
| **Personnel and Training Required:** | Interviewers must be trained and found competent to conduct personal interviews with individuals from the general population. |
| **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:** | Self-administered or interviewer-administered questionnaire  |
| **Derived Variables:** | None |
| **Requirements:** |

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| **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 |

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| **Annotations for Specific Conditions:** | None |
| **Process and Review:** | Not applicable.  |