

About the Measure

<p>Domain:</p> <p>(included in Community Outreach and Supplemental Information)</p>	<p>The name of the domain.</p>
<p>Measure:</p> <p>(included in Community Outreach and Supplemental Information)</p>	<p>The name of the measure as recommended by the WG. This is not the name of the protocol. The name may be changed by an Expert Review Panel, if necessary.</p> <p>Reminder: A measure refers broadly to a standardized way of capturing data on a certain characteristic of or relating to a study subject. Measures may include exposures, clinical assessments, and quantitative and qualitative traits.</p>
<p>Definition:</p> <p>(included in Community Outreach and Supplemental Information)</p>	<p><u>Definition:</u> A very brief overview of the measure. This can include that the measure is a questionnaire, bioassay or physical assessment. It can also include a brief definition of the measure concept if it is not immediately obvious.</p>
<p>Purpose:</p> <p>(included in Community Outreach and Supplemental Information)</p>	<p><u>Definition:</u> This section describes how this measure is used and why this measure is important to health research. This can include the following:</p> <ul style="list-style-type: none"> • describing how the measure is used in population studies (e.g., the measure is used to screen and individual for a condition; the measure is used to assess the symptoms of a condition) • describing how the measure is related to specific health conditions or diseases. <p>The purpose should describe the measure, <i>not the protocol</i>.</p>
<p>Essential PhenX Measures:</p> <p>(included in Community Outreach)</p>	<p><u>Definition:</u> Essential PhenX Measures are PhenX measures that are critical to the collection of the measure or are necessary for the interpretation of results. Essential measures are integral to the measure. Without such information the data collected would be incomplete and/or misleading. Examples include the following :</p> <ul style="list-style-type: none"> • PhenX measures that are intrinsic to or inseparable from the chosen PhenX measure. An example would be the Race and Ethnicity measures, which could easily have been combined into a single Race/Ethnicity measure. Race and Ethnicity are essential measures for each other. • PhenX measures that have a hierarchical relationship with the chosen measure. For example, in the Alcohol, Tobacco and Other Substances (ATOS) measures, a gateway question is asked, such as “Have you ever used alcohol, tobacco or other illicit substances?” A “yes” response requires a follow-up question about usage in the last 30 days. In this case, the "gateway" measure is an essential measure for all other alcohol measures in the domain. • PhenX measures that are fundamentally required for interpretation and final analysis of the measure. For example, the Current Age and Gender measures are necessary to interpret the value collected for the Current Height measure. Current Age and Gender would be listed as essential measures for Current

	<p>Height</p> <p>Essential Measures and Related PhenX Measures do not overlap.</p>
<p>Related PhenX Measures:</p> <p>(included in Community Outreach)</p>	<p><u>Definition:</u> A Related PhenX Measure is an additional PhenX measure that the Working Group thinks may be of interest to the user. Related PhenX Measures may include measures from one or more of the following subcategories:</p> <ul style="list-style-type: none"> • Additional measures, which are needed to calculate a derived variable (e.g., the Weight and Height measures for body mass index [BMI]). • Measures that are conceptually related to the chosen measure (e.g., Current Educational Attainment is conceptually related to Annual Family Income, and Arm Span is conceptually related to Height). • Measures that are physiologically and/or biologically related to the chosen measure (e.g., Stroke and Heart Disease). <p>Related PhenX Measures can include PhenX measures from other domains. Related PhenX Measures and Essential Data do not overlap.</p>
<p>Keywords:</p> <p>(included in Community Outreach)</p>	<p><u>Definition:</u> This is a concise list of terms (words or phrases) that a researcher might use to search the PhenX Toolkit and find this measure. The smart search function of the Toolkit will primarily use this field. Therefore, please include any useful keywords found in the Source and/or General Reference, Protocol Text, Description of Protocol, and other sections that will provide the proper context for a researcher to locate this measure. Use the following guidelines:</p> <ol style="list-style-type: none"> 1. include full name and abbreviation of the source (e.g., 2013-2014 National Health and Nutrition Examination Survey, NHANES) 2. include full name of funding agency and acronym (e.g., Centers for Disease Control and Prevention, National Center for Health Statistics (CDC/NCHS)) 3. include name of domain 4. include “proprietary” if applicable to protocol 5. include medical conditions related to the measure (if found elsewhere in datasheet) OR added via the annotation tool 6. exclude essential or related measures 7. exclude distantly related keywords 8. exclude broad-based conditions (e.g., cancer, cardiovascular) unless measure is in that domain 9. exclude terms that can be found in “full text” search, e.g. instrument name, source study name (except for abbreviation of the study names) and institute 10. exclude measure name 11. exclude search filter words (interview, infant, child) <p><i>See keywords in ERP 1 measures (Anthropometrics, Diabetes, Physical Activity and Physical Fitness, Nutrition and Dietary Supplements) for examples.</i></p>
<p>Measure Release Date:</p>	

About the Protocol

(Please fill out a new table for each alternate protocol; this will make the data loading <i>much</i> faster.)	
Protocol Release Date:	
PhenX Protocol Name: <small>(included in Community Outreach)</small>	The name applied to the protocol for use in the Toolkit. For example, the “Temperament – Child Protocol” applies to children and “Temperament – Infant Protocol” applies to infants.
Protocol Name from Source: <small>(included in Community Outreach)</small>	<p>The full title of the protocol with the acronym, if applicable, in parentheses. If there is no true protocol name use general description of the source. Include the date of the protocol if there are multiple versions of the protocol.</p> <p>There are differences between the Protocol Name and the Source. For example, the Source is a more well-defined or formal description and includes funding agency, date, and other information such as questions numbers of the instrument. The Source does not always include the name of the protocol.</p> <p>If the source is a publication include the entire publication as it appears in the Source section of the datasheet.</p> <p>Examples: Women’s Health Initiative (WHI) Objective Physical Activity and Cardiovascular Health (OPACH) Accelerometer Protocol</p> <p>Jurca, R., Jackson, A. S., LaMonte, M. J., Morrow J. R., Blair, S. N., Wareham, N. J., . . . Laukkanen, R. (2005). Assessing cardiorespiratory fitness without performing exercise testing. <i>American Journal of Preventive Medicine</i>, 29(3), 185-193.</p>
Description: <small>(included in Community Outreach and Supplemental Information)</small>	<p><u>Definition:</u> A general description of the referenced protocol and how it is administered. This can include number of questions, style of questions (yes/no or Likert style) mode of administration (self-report or interviewer administered) appropriate age ranges. Scoring instructions may also be included here</p>
Specific Instructions: <small>(included in Community Outreach)</small>	<p><u>Definition:</u> This section <i>does not</i> include any instructions that are part of the protocol. Any instructions for completing the protocol that come from the original instrument should be included in the protocol text section.</p> <p>The Specific Instructions section includes additional directions <i>from the Working Group (WG) or the Expert Review Panel (ERP)</i> for completing the protocol. This section can include any of the following:</p> <ol style="list-style-type: none"> 1. Any quality control instructions required for this protocol, including taking measurements in duplicate, rounding rules, and whether the investigator should record the protocol used. 2. The relationship of this protocol to other protocols in the PhenX Toolkit: 3. The relationship of this protocol to other protocols in this measure: 4. The relationships of the individual parts of the protocol to one another: 5. Instructions for obtaining copyrighted or proprietary protocols: 6. Indicate that the protocol can be administered to other groups/populations than what was described originally by source.

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	7. Annotations from a crowdsourcing effort (e.g., Rare Genetic Conditions).
Protocol: (included in Community Outreach and Supplemental Information)	Insert the protocol here. Include all general instructions for completing the protocol in this section (not Specific Instructions). Remove any programming (CAPI) instructions from the protocol. Notes: <ol style="list-style-type: none"> 1. The protocol text can be as long as necessary. 2. May include images, footnotes, comments and trademark information. 3. Include algorithms to score the protocol at the end of this section. 4. Each time a trademarked product name is listed, denote it either with TM or ®. Also include a footnote that states the company that holds each trademark. 5. PhenX programmers employ a standard formatting that will be applied to all protocol text.
Selection Rationale: (included in Community Outreach)	Definition: A brief explanation of why the Working Group selected this particular protocol and why it was preferred over other similar protocols. This explanation can include the following: <ul style="list-style-type: none"> • the advantages of using this protocol in epidemiological research, • a description of the validity of the protocol, • a description of how well-established the protocol is or of how it was used or applied in the original study.
Source: (included in Community Outreach and Supplemental Information)	Definition: This provides the source of the protocol. Any instruments or questionnaires that are used in the Protocol Text section should be referenced here and not in the General References section. Recommended citation formats are American Psychological Association (APA) http://www.apastyle.org/ or the OWL at Purdue's resource for APA formatting http://owl.english.purdue.edu/owl/resource/560/01/ <i>Do not include/list web addresses or URLs, even if the source is available on-line. Do not include DOIs. These links are often broken and useless. There may be exceptions to this rule but the use of web addresses and URLs should be minimized. An alternative is to post the document to Supplemental Information and include a link to the document.</i> <u>Formatting Instructions for Large Studies, such as NHANES, MESA, CARDIA, etc.:</u> For instruments / questionnaires that are completely on-line resources, include: <ul style="list-style-type: none"> • the name of the funding agency, • the name of the instrument / questionnaire, • the date of the instrument / questionnaire, • the specific module of the instrument / questionnaire if there is one and • the specific question numbers from the instrument / questionnaire followed by the corresponding protocol question number in parentheses. An example from NHANES follows.

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	Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey (NHANES), 2013-2014, Demographics Module, question numbers DMQ.263, DMQ.336, DMQ.350, DMQ.266.
Life Stage: (included in Community Outreach)	A category that describes the age and development of the study population in the original source who can complete the given protocol. These are the same as listed in the Toolkit search function for Life Stage and include: Infant Toddler Child Adolescent Adult Senior Pregnancy Any Age If this information is not available, record "Unavailable". Examples: If the protocol calls for an individual age 2 and over then all the categories for Toddler through Senior would be entered. If the protocol is applicable to an individual of any age but not pregnancy, enter "Any Age".
Language: (included in Community Outreach and Supplemental Information)	<u>Definition:</u> This section is a comma separated list of languages available for the referenced protocol. Additional text (descriptions, explanations) will not be displayed in the toolkit. If this information is not available, record "Unavailable".
Participant: (included in Community Outreach and Supplemental Information)	<u>Definition:</u> Based on the source, the age and characteristics (e.g., gender) of a respondent or participant who can answer the question(s) or complete the protocol. If the WG/ERP recommends that the protocol can be used with a population with different characteristics than the original, it should be noted in the Specific Instructions section.
Personnel and Training Required: (included in Community Outreach and Supplemental Information)	<u>Definition:</u> This section describes the personnel and training required to administer the referenced protocol. For self-administered or proxy-administered questionnaires, this section should be "None". For interviewer-administered questionnaires, please use the following text: "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."

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	No more than 3-4 sentences of simple text.
<p>Equipment Needs: (included in Community Outreach and Supplemental Information)</p>	<p><u>Definition:</u> This section lists any equipment required to administer the referenced protocol. For self- or proxy- administered questionnaires, this section should be "None". For interviewer-administered questionnaires, please use the following text:</p> <p>"The PhenX Working Group acknowledges these questions can be administered in a computerized or noncomputerized format (i.e., paper-and-pencil instrument). Computer software is necessary to develop computer-assisted instruments. The interviewer will require a laptop computer/handheld computer to administer a computer-assisted questionnaire."</p> <p>No more than 2-3 sentences of simple text. Can be just a list of the required equipment. Insert "None" if protocol requires no equipment.</p>
<p>General References: (included in Community Outreach and Supplemental Information)</p>	<p>This section includes any additional references used to develop this protocol for the PhenX Toolkit.</p> <p><u>General Formatting Instructions:</u> Recommended citation formats are American Psychological Association (APA) http://www.apastyle.org/ or the OWL at Purdue's resource for APA formatting http://owl.english.purdue.edu/owl/resource/560/01/</p> <p><i>Do not include/list web addresses or URLs, even if the source is available on-line. Do not include DOIs. These links are often broken and useless. There may be exceptions to this rule but the use of web addresses and URLs should be minimized. An alternative is to post the document to Supplemental Information and include a link to the document.</i></p> <p><u>Formatting Instructions for Large Studies, such as NHANES, MESA, CARDIA, etc.:</u> For instruments / questionnaires that are completely on-line resources, include:</p> <ul style="list-style-type: none">• the name of the funding agency,• the name of the instrument / questionnaire,• the date of the instrument / questionnaire,• the specific module of the instrument / questionnaire if there is one and• the specific question numbers from the instrument / questionnaire followed by the corresponding protocol question number in parentheses.
<p>Mode of Administration: (included in Community Outreach and Supplemental Information)</p>	<p><u>Definition:</u> This section indicates whether the protocol is, for example, a question, physical measurement, or clinical measurement. Please complete this section with one of the options from the following list:</p> <ul style="list-style-type: none">• Self- or proxy- administered questionnaire• Interviewer-administered questionnaire• Bioassay• Clinical Assessment

	<ul style="list-style-type: none"> • Physical Examination • Secondary data analysis <p><u>If this information is not available, record “Unavailable”.</u></p>										
<p>Derived Variables: (included in Community Outreach)</p>	<p><u>Definition:</u> A derived variable is a variable that is frequently calculated from <i>this</i> PhenX measure or from a combination of this PhenX measure with other PhenX measures or non-PhenX measures. For instance, body mass index (BMI) is a common derived variable calculated using the Height and Weight measures. Consequently, BMI is listed as a derived variable for the PhenX measures Height and Weight. A derived variable may require additional non-PhenX measure data.</p> <p>Derived Variables should include a description of the variable (can be an equation) and a reference describing its use or development.</p>										
<p>Requirements: (included in Community Outreach)</p>	<p>A “Yes” response in any of the categories means that the measure is <i>high</i> burden and counts as one of the four high-burden measures that can go to outreach and/or one of the two high-burden measures that can go to the Toolkit.</p> <table border="1" data-bbox="493 957 1416 1293"> <thead> <tr> <th>Requirements Category</th> <th>Required (Yes/No):</th> </tr> </thead> <tbody> <tr> <td>Major equipment</td> <td>No</td> </tr> <tr> <td>Specialized training</td> <td>No</td> </tr> <tr> <td>Specialized requirements for biospecimen collection</td> <td>Yes</td> </tr> <tr> <td>Average time of greater than 15 minutes in an unaffected individual</td> <td>Yes</td> </tr> </tbody> </table> <p><u>Equipment:</u> This measure requires a specialized measurement device that may not be readily available in every setting where genome-wide association studies are being conducted. Examples of specialized equipment are DEXA, Echocardiography, and Spirometry.</p> <p><u>Training:</u> This measure requires staff training in the protocol methodology and/or in the conduct of the data analysis.</p> <p><u>Biospecimen:</u> This protocol requires that blood, urine, and so forth be collected from the study participants. These biospecimens will also entail costs for analysis. Note that this definition will change based on the Steering Committee decision that bioassays are low burden unless the collection of the biospecimen is highly burdensome (e.g., the collection requires fasting or has specific handling requirements); lab test and cost of assay do not figure into it.</p> <p><u>15 Minutes:</u> This measure is expected to take greater than an average of 15 minutes of an affected respondent’s time.</p>	Requirements Category	Required (Yes/No):	Major equipment	No	Specialized training	No	Specialized requirements for biospecimen collection	Yes	Average time of greater than 15 minutes in an unaffected individual	Yes
Requirements Category	Required (Yes/No):										
Major equipment	No										
Specialized training	No										
Specialized requirements for biospecimen collection	Yes										
Average time of greater than 15 minutes in an unaffected individual	Yes										

Annotations for Specific Conditions:	Add annotations for specific conditions here. If there are no annotations the default is "No annotations at this time."
Process and Review:	<p>Notes from the review of the measure and protocol by the Expert Review Panel (ERP). If the ERP has not reviewed the measure yet record "The Expert Review Panel has not reviewed this measure yet." If the measure has been reviewed complete items a. through e. below.</p> <p>a. Indicate which ERP reviewed the measure with a link to roster <i>Example:</i> The Expert Review Panel #1 reviewed the measures in the Anthropometrics, Diabetes, Physical Activity and Physical Fitness, and Nutrition and Dietary Supplements domains. Add summary notes about the changes the ERP made to the measure. <i>Options:</i> Guidance from the ERP includes::</p> <ul style="list-style-type: none"> • Added a new measure • Added a new protocol • Added recommendations on use of serum or plasma • Changed name of measure • Changed unit of measurement • New Data Dictionary • No significant changes • Revised descriptions of measure • Replaced the protocol (different source)* • Added replicate measure language • Updated the protocol (same source)* • No changes <p>*If protocol was updated/replaced or the measure was retired, must provide rationale.</p> <p>b. Back-compatibility: if the protocol has been updated or replaced indicate the degree of compatibility between the two protocols. If there was no change to the actual protocol record "NA". These changes may affect the Data Collection Worksheet (DCW) and Data Dictionary (DD).</p> <ul style="list-style-type: none"> ▪ Back-compatible (updated/very similar protocol which would require no changes to data dictionary) ▪ Partially back-compatible (updated/similar protocol which would require some changes to the data dictionary), variable mapping between current and previous protocols can be found here <link> ▪ Not back-compatible (vastly different than previous protocol which would require a new data dictionary) and not recommended for use (discredited or no longer considered broadly validated) <p><i>Example:</i> Back-compatible: no changes to Data Dictionary</p> <p>c. Archiving measures and protocols: if, based on the ERP review, a measure has been changed it will be placed in the Toolkit archive. A link to the archive appears.</p>

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	<p><i>Example:</i> Previous version in Toolkit archive (link)</p>
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