## Pregnancy Measures for PhenX Toolkit

*Dr. Siobhan Dolan of Albert Einstein College of Medicine was chair of the Pregnancy Working Group.*

<table>
<thead>
<tr>
<th>Measure</th>
<th>Collection Mode</th>
<th>Description of Measurement Protocol</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Adequacy of Prenatal Care</td>
<td>Medical Records Abstraction</td>
<td>Dates of prenatal care visits are abstracted from medical record or birth certificate data.</td>
</tr>
<tr>
<td>2 Concentrations of Flame Retardants</td>
<td>Bioassay</td>
<td>Blood is collected from the subject in a pre-screened 10 ml red-top tube, centrifuged, and the serum is transported on dry ice to the laboratory. Analysis is by isotope-dilution high-resolution mass spectrometry (ID-HRMS). This device measures concentrations of polychlorinated diphenyl ethers (PCBs) in serum.</td>
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<tr>
<td>3 Concentrations of Phenols and Parabens</td>
<td>Bioassay</td>
<td>Urine is collected from the subject in a pre-screened 120 ml urine container and then placed in a refrigerator or on ice packs immediately after collection. Transfer to polypropylene vial. Transport or ship urine samples on dry ice. Place urine samples in a -70°C freezer and store until shipment or analysis. Thaw sample, and perform analysis via on-line solid phase extraction-high performance liquid chromatography-isotope dilution-tandem mass spectrometry (SPE-HPLC-isotope dilution-MS/MS).</td>
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<tr>
<td>4 Concentrations of Polychlorinated Biphenyls (PCBs) and Persistent Pesticides</td>
<td>Bioassay</td>
<td>Blood is collected from the subject in a pre-screened 3 ml red top tube and is not inverted or mixed and kept upright on a tube rack for 20-30 minutes to allow to coagulate. Centrifuge the red-top tubes for 10 minutes, transfer to Wheaton Bottle, and cap. Place serum samples in a -20°C freezer and store until shipment. Analysis is by high-performance liquid chromatography/isotope-dilution high-resolution mass spectrometry (HRGC/ID-HRMS). This device measures concentrations of polychlorinated biphenyls (PCBs) and persistent pesticides in serum.</td>
</tr>
<tr>
<td>5 Concentrations of Trace Metals</td>
<td>Bioassay</td>
<td>Blood is collected from the subject in a pre-screened 3 ml lavender top tube and then refrigerated until analyses by high-performance liquid chromatography coupled to inductively coupled plasma dynamic reaction cell mass spectrometry (ICP-DRC-MS). This device measures concentrations of cadmium, lead, manganese, selenium, and mercury in the blood.</td>
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<tr>
<td>6 Current Pregnancy Status</td>
<td>Bioassay</td>
<td>Human chorionic gonadotropin (hCG) is a hormone the placenta produces shortly after fertilization. Within 7-10 days of conception, hCG can be detected in urine or blood samples. Levels of hCG rise quickly through early pregnancy and peak at 10-12 weeks in the 100,000 to 200,000 mIU/mL range. Standard urine collection procedures from the National Children’s Study are described in the protocol. An immunoassay was used during National Health and Nutrition Examination Survey (NHANES) to rapidly detect pregnancy in adolescents and adults.</td>
</tr>
<tr>
<td>7 Difficulties in Pregnancy</td>
<td>Self-report</td>
<td>A single-item (with 13 subscales), Likert-style self-report questionnaire used to capture information about a woman’s pregnancy. This questionnaire is administered twice: once at 6-13 weeks, and again at 22-29 weeks.</td>
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<tr>
<td>8 Family History of Pregnancy Complications</td>
<td>Interview</td>
<td>A two-item, multi-part set of interviewer-administered questions about the woman's family members who have had pregnancy complications. The relationship between the woman and her family members and the list of pregnancy complications are coded.</td>
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<tr>
<td>9 Fetal Growth Assessment</td>
<td>Medical Records Abstraction</td>
<td>Determination of fetal growth is a three-step process: Step 1: Ascertainment of estimated fetal weight (EFW) at which the EFW was recorded Step 2: Verification of gestational age (GA) at which the EFW was recorded Step 3: Determination of EFW or biometry percentiles by plotting the EFW or relevant biometric measures at the appropriate GA on a pre-defined fetal growth curve</td>
</tr>
<tr>
<td>10 Gestational Age</td>
<td>Interview</td>
<td>Twelve questions about whether the woman was trying to get pregnant or had infertility treatment; dates for the last menstrual cycle, first prenatal visit and first ultrasound, and estimates of the delivery date.</td>
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<tr>
<td>11 Gestational Diabetes</td>
<td>Medical Records Abstraction</td>
<td>This is a medical records abstraction form that collects information on glucose screening, glucose tolerance testing, HgbA1c testing, and fasting glucose testing during pregnancy.</td>
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<tr>
<td>12 Health and Wellness in Pregnancy</td>
<td>Interview</td>
<td>A woman is asked about her general physical and mental health during the 3 months before and during her pregnancy. The five Likert-style administered questions are from the Early Life Exposure Assessment Tool (ELEAT).</td>
</tr>
<tr>
<td>13 Mode of Conception</td>
<td>Medical Records Abstraction</td>
<td>Information about the woman’s use of fertility treatments or fertility drugs or in vitro fertilization procedures is abstracted from the medical record.</td>
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<tr>
<td>14 Mode of Delivery</td>
<td>Interview</td>
<td>A woman who gave birth is asked several questions about how the baby was delivered.</td>
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<tr>
<td>15 Prenatal and Postpartum Depression</td>
<td>Self-report</td>
<td>The Edinburgh Postnatal Depression Scale© (EPDS) was developed to screen prenatal and postpartum women for the indication of depression. This 10-question self-report instrument is designed to screen for depression in the previous 7 days.</td>
</tr>
</tbody>
</table>

Complete measurement protocols are available at [https://www.phenxtoolkit.org](https://www.phenxtoolkit.org).
What is the PhenX Toolkit?

The PhenX Toolkit is an online catalog of recommended, standard measures and is available for use at no cost at https://www.phenxtoolkit.org.

The purpose of the PhenX Toolkit is to:

- Provide recommended, standard measures of phenotypes and exposures for use in biomedical research
- Facilitate acceptance and use of standard PhenX measures
- Promote collaboration and facilitate cross-study analyses

Researchers visit the Toolkit to:

- Select and incorporate standard measures into ongoing studies
- Consider PhenX measures when planning new studies
- Review and select high-quality, recommended, standard measures in order to expand a study beyond the primary research focus
- Review and select PhenX measures that relate to researchers’ primary research focus

PhenX Toolkit features:

- The Smart Query Tool provides two search options: a Smart Search based on keywords (and synonyms) and a Text Search that searches all text
- Browse options: Domains, Measures, Collections, Supplemental Information, and hierarchical tree view
- Link your study to find other researchers using the same measures and to explore opportunities for cross-study analysis
- Standards included: cancer Data Standards Registry and Repository (caDSR) Common Data Elements (CDEs); Logical Observation Identifiers Names and Codes (LOINC)
- Registered Users have access to additional features and functionality (e.g., saving more than one "My Toolkit")
- Quick Start and Tutorial resources help new users become familiar with the Toolkit
- Data Dictionaries compatible with submission to the database of Genotypes and Phenotypes (dbGaP) and Custom Data Collection Worksheets can be downloaded
- REDCap Instrument Zip files for PhenX protocols can be uploaded directly to REDCap

For each PhenX measure, the following information is provided:

- Brief description of the measure
- Rationale for selecting the measure for inclusion in the Toolkit
- Detailed protocol(s) for collecting the measure
- Information about the personnel, training, and equipment needed to collect the measure
- Any special requirements
- Related measures
- References

PhenX Research Domains

- Alcohol, Tobacco and Other Substances
- Anthropometrics
- Cancer
- Cardiovascular
- Demographics
- Diabetes
- Environmental Exposures
- Gastrointestinal
- Infectious Diseases and Immunity
- Neurology
- Nutrition and Dietary Supplements

- Obesity
- Ocular
- Oral Health
- Physical Activity and Physical Fitness
- Pregnancy
- Psychiatric
- Psychosocial
- Rare Genetic Conditions
- Reproductive Health
- Respiratory
- Skin, Bone, Muscle and Joint
- Social Environments
- Speech and Hearing

PhenX supplements:

Several National Institutes of Health (NIH) institutes and programs have contributed supplemental funding to add depth to the Toolkit in specific areas of research.

PhenX Measures for Sickle Cell Disease Research funded by the National Heart, Lung, and Blood Institute (NHBLI).

PhenX Measures for Tobacco Regulatory Research were supported by NIH and the Food and Drug Administration’s Center for Tobacco Products (CTP).

PhenX Measures for Mental Health Research funded by the National Institute of Mental Health (NIMH).

PhenX Measures for Substance Abuse and Addiction Research funded by the National Institute on Drug Abuse (NIDA).

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Dr. Carol M. Hamilton is the RTI International Principal Investigator, and Dr. Erin M. Ramos is the NHGRI Project Scientist.

More information is available at the project web portal: https://www.phenx.org

1 Funding for the Social Environments domain provided by the Office of Behavioral and Social Sciences Research (OBSSR).