PhenX Toolkit

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

The following is a summary version of the full National Health and Nutrition Examination Survey (NHANES) 2007–2008 protocol.

Exclusion Criteria

Persons will be **excluded** from this component if they:

Report that they have hemophilia; or

Report that they have received cancer chemotherapy in the last 4 weeks

SP = Sample Person.

1. Do you have hemophilia?

1 [ ] Yes

2 [ ] No

7 [ ] Refused

9 [ ] Dont Know

If the SP answers, "Yes," the SP is excluded from the blood draw.

If SP answer "No" or "Dont Know," blood is drawn from the SP.

2. Have you received cancer chemotherapy in the past four weeks or do you anticipate such therapy in the next four weeks?

1 [ ] Yes

2 [ ] No

7 [ ] Refused

9 [ ] Dont Know

If the SP answers, "Yes," the SP is excluded from the blood draw.

If SP answer "No" or "Dont Know," blood is drawn from the SP.

Note from the Skin, Bone, Muscle and Joint Working Group: The investigator should record the reason a person is excluded from the blood draw.

Venipuncture Procedures

Please review chapter 4 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey 2007–2008 for a full description of phlebotomy procedures. [alink[NHANES_Lab_Manual.pdf|2007-2008 NHANES Lab Manual]]

Venipuncture should generally be performed using the median cubital, cephalic, or basilic veins in the left arm unless this arm is unsuitable. If the veins in the left arm are unsuitable, look for suitable veins on the right arm. If the veins in the antecubital space on both arms are not suitable, then look for veins in the forearm or dorsal side of the hand on the left arm/hand and then the right arm/hand.

Note from the Skin, Bone, Muscle and Joint Working Group: Blood should be collected in an appropriate 5-mL or 10-mL red-top tube or serum separator tube.

Recording the Results of the Venipuncture Procedure

Immediately after completing the venipuncture, record the results of the blood draw, the reasons for a tube not being drawn according to the protocol, and any comments about the venipuncture.

Blood Processing

Please review chapter 8 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey 2007–2008 for a full description of blood processing procedures. [alink[NHANES_Lab_Manual.pdf|2007-2008 NHANES Lab Manual]]

Allow the blood to clot by setting aside for 30 to 45 minutes at room temperature. Do not clot for more than an hour.

Centrifuge the tube at room temperature to separate the serum and aliquot into an appropriate storage tube.

Determine whether the serum is hemolyzed, turbid, lipemic, or icteric. If so, enter a comment to describe the plasma.

Sample Storage

Note from the Skin, Bone, Muscle and Joint Working Group: Serum should be stored at -80C until testing and shipped on dry ice to prevent thawing.

Lab Assay for Serum Concentration of Alkaline Phosphatase

The Skin, Bone, Muscle and Joint Working Group recommends that alkaline phosphatase concentration be determined by a kinetic rate method. In this reaction, the concentration of the alkaline phosphatase is measured (in international units per liter; IU/L) by monitoring the ability of the enzyme to change a colorless organic phosphate substrate into a yellow colored product. The National Health and Nutrition Examination Survey 2007–2008 includes two examples of this method:

[alink[Alkaline_Phosphatase_DXC800.pdf|2007 –2008 NHANES Alkaline Phosphatase Lab Assay #1]]

[alink[Alkaline_Phosphatase_LX20.pdf|2007–2008 NHANES Alkaline Phosphatase Lab Assay #2]]

Note from the Skin, Bone, Muscle and Joint Working Group: To aid comparability, the Working Group recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

Reference Ranges for Alkaline Phosphatase*

Serum or Plasma Age Group	**IU/L**
0–5 Y	60–321
5–10 Y	110–360
10–12 Y	103–373
12–16 Y	67–382
>16 Y	36–113

* From the National Health and Nutrition Examination Survey 2007–2008 laboratory

protocol.

Protocol source: https://www.phenxtoolkit.org/protocols/view/170101