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 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 [ ] Don't Know

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

If SP answers "No" or "Don't 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 [ ] Don't Know

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

If SP answers "No" or "Don't Know," blood is drawn from the SP.

Venipuncture Procedures

Editor's Note: Please review chapter 4 of the *Laboratory Procedures Manual* from the 2009-2010 National Health and Nutrition Examination Survey (NHANES) for a full description of phlebotomy procedures. This manual is posted here, and is also available at the NHANES website: www.cdc.gov/nchs/data/nhanes/nhanes_09_10/lab.pdf

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.

Fill a 3 or 4 ml K_3 EDTA tube with blood.

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. Collection tube should be standardized across the study duration.

Laboratory Assay for Ferritin

The Sickle Cell Disease Cardiovascular, Pulmonary, and Renal Working Group notes that there are a number of different assays and instruments that are appropriate to measure ferritin. Once an assay is chosen for a particular study, the Working Group recommends that no changes in the protocol be made over the course of the study. 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 (Normal Values) for Ferritin

Ferritin reference ranges are assay-specific. The Roche Diagnostics kit used by NHANES specifies expected values of 30-400 ng/mL for men and 13-150 ng/mL for women.

Note: A full description of the National Health and Nutrition Examination Survey procedure for serum ferritin testing can be found in the 2009-2010 *Laboratory Procedure Manual* posted here, and is also available at the NHANES website: www.cdc.gov/nchs/data/nhanes/nhanes_09_10/FERTIN_F_met_ferritin.pdf

Protocol source: https://www.phenxtoolkit.org/protocols/view/811301