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 2007-2008 protocol.

Exclusion Criteria

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

• Report that they have hemophilia; • Report that they have received cancer chemotherapy in the last 3 weeks; and • Report that they have not fasted at least 9 hours.

SP = Sample Person.

1. Did you eat or drink anything other than plain water after [Insert time at 9 hours prior to sample collection] last night?

[ ] Yes

[ ] No

[ ] Refused

[ ] Don’t Know

If the answer is "No," then he or she **has met** the 9-hour fast. If the answer is "Yes," "Don’t know," or "Refused," then the actual fasting time is unknown.

Confirmation Question:

2. Have you had any of the following since {insert time from 1 here}?

Coffee or tea with cream and sugar? [Include milk or non-dairy creamers.]

[ ] Yes If Yes, record time and date _____

[ ] No

Alcohol, such as beer, wine, or liquor?

[ ] Yes If Yes, record time and date _____

[ ] No

Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?

[ ] Yes If Yes, record time and date _____

[ ] No

Antacids, laxatives, or anti-diarrheals?

[ ] Yes If Yes, record time and date _____

[ ] No

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

[ ] Yes If Yes, record time and date _____

[ ] No

3. 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 the SP answers "No" or "Don’t Know," blood is drawn from the SP.

4. Have you received cancer chemotherapy in the past 4 weeks or do you anticipate such therapy in the next 4 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 the 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 National Health and Nutrition Examination Survey for a full description of Phlebotomy procedures. 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.

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

Editor's Note: 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: 2007-2008 NHANES Lab Manual.

• Allow the blood to clot by setting aside for 30-45 minutes at room temperature. Do not clot for more than 1 hour.

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

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

Laboratory Assay for Serum Insulin

The Diabetes Working Group (WG) notes that although there is not a standardized assay, there are a number of different kits that are appropriate to measure the concentration of insulin in serum. Once an assay is chosen for a particular study, the WG recommends that no changes in the protocol be made over the course of the study. To aid comparability, the Diabetes WG recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

Reference Ranges:

Concentrations of fasting insulin normally ranges between 3 uU/mL and 17 uU/mL.

Protocol source: https://www.phenxtoolkit.org/protocols/view/141301