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.

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

Venipuncture Procedures

Editors 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: http://www.cdc.gov/nchs/data/nhanes/nhanes_07_08/manual_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.

Record 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.

Process the Sample for the Cystatin C Assay

Editors 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:

http://www.cdc.gov/nchs/data/nhanes/nhanes_07_08/manual_lab.pdf

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

Laboratory Assay for Cystatin C

The Diabetes Working Group notes that although there is not a standardized assay, there are many different kits which are appropriate to measure the concentration of cystatin C in serum. 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.

Reference Ranges

Cystatin C ranges between 0.57 - 1.12 mg/L

Estimated Glomerular Filtration Rate:

estimated Glomerular Filtration Rate = 127.7 X Cystatin C -1.17 X Age -0.13 X [0.91 if Female] X [1.06 if African American]

Protocol source: https://www.phenxtoolkit.org/protocols/view/250701