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

2. 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 [ ] 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.

Note from the Infectious Diseases and Immunity Working Group (WG): The investigator should record the reason a person is excluded from the blood draw.

Venipuncture Procedures

Editors Note: Please review chapter 4 of the Laboratory Procedures Manual from the NHANES 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 basilica 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 right arm/hand.

The Infectious Diseases and Immunity WG recommends that 3 mL serum be collected from each participant.

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.

Note from the Infectious Diseases and Immunity WG: The Infectious Diseases and Immunity WG recommends that the investigator record whether the blood was drawn and whether the full amount was obtained.

Process the Sample for the Serum

Editors Note: Please review chapter 8 of the Laboratory Procedures Manual from the NHANES 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 30–45 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 Cytokine Panel 12

The Infectious Diseases and Immunity WG recommend the multi-analyte fluorescent detection (MAFD) method of Cytokine Panel 12 offered through ARUP Laboratories.

To aid comparability, the Infectious Diseases and Immunity WG recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

Reference Interval

Components	**Reference Interval**
Interleukin-2 Receptor (Soluble) by MAFD	0–1,033 pg/mL
Interleukin-12 by MAFD	0–6 pg/mL
Interferon-gamma by MAFD	0–5 pg/mL
Interleukin-4 by MAFD	0–5 pg/mL
Interleukin-5 by MAFD	0–5 pg/mL
Interleukin-10 by MAFD	0–18 pg/mL
Interleukin -13 by MAFD	0–5 pg/mL
Interleukin-1 beta by MAFD	0–36 pg/mL
Interleukin-6 by MAFD	0–5 pg/mL
Interleukin-8 by MAFD	0–5 pg/mL
Tumor Necrosis Factor – alpha	0–22 pg/mL

Interleukin-2 by MAFD	0–12 pg/mL

Protocol source: https://www.phenxtoolkit.org/protocols/view/160201