



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

Note from the Gastrointestinal WG: The investigator should record the reason a person is excluded from the blood draw.

Venipuncture Procedures

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.

For a full description of phlebotomy procedures, please refer to Chapter 4 in the downloadable PDF of the 2009-2010 National Health and Nutrition Examination Survey (NHANES) Laboratory Procedures Manual available here:
[alink[NHANES_2009-2010_LabManual.pdf|NHANES 2009-2010 Lab Manual]]

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.

For a full description of blood processing procedures, please refer to Chapter 8 in the downloadable PDF of the 2009-2010 National Health and Nutrition Examination Survey (NHANES) Laboratory Procedures Manual available here:
[alink[NHANES_2009-2010_LabManual.pdf|NHANES 2009-2010 Lab Manual]]

The serum processing protocol is displayed in Exhibit 8.6.

Laboratory Assay

Note from the Gastrointestinal WG: Although there is not a standardized assay, there are a number of different kits that are appropriate to measure the concentration of TTG and EMA 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 Gastrointestinal WG recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

Reference Intervals

TTG:

19 Units or less = Negative

20-30 Units = Weak Positive

31 Units or greater = Moderate to Strong Positive

EMA: < 1:10

Protocol source: <https://www.phenxtoolkit.org/protocols/view/190301>