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.

Administer the following questions prior to blood collection.

1. Do you have hemophilia or any bleeding disorder?

[ ] Yes

[ ] No

[ ] Don't Know

[ ] Refused

• If the participant answers "Yes" or "Don't know," or refuses to answer, **blood will not be collected.**

2. Have you had cancer chemotherapy within the past 4 weeks?

[ ] Yes

[ ] No

[ ] Don't Know

[ ] Refused

• If the participant answers "Yes" or "Don't know," or refuses to answer, **blood will not be collected.**

3. Have you had any problems with a blood draw in the past?

[ ] Yes

[ ] No

[ ] Don't Know

[ ] Refused

• If the participant answers "Yes," go to question 4.

• If the participant answers "No," "Don’t know," or refuses to answer, go to question 5.

4. What problems have you had with a blood draw in the past?

_____

• Record the types of problems that the participant experienced during previous blood draws.

• If the participant refuses to answer or does not remember specifically what type of problem was experienced in the past, record and go to question 5.

5. When was the last time you had anything to eat or drink other than water?

Date _____ mm/dd/yyyy

Time _____ am/pm

6. Have you had sweetener or milk added to a drink, such as coffee or tea, in the last 8 hours?

[ ] Yes

[ ] No

[ ] Don’t Know

[ ] Refused

• Record the participant’s response.

• "Sweetener" includes sugar, honey, and flavored creamers. If the participant consumed an artificial sweetener in coffee, tea, or a diet soda, record "No."

7. Have you had alcohol such as beer, wine, or liquor in the last 8 hours?

[ ] Yes

[ ] No

[ ] Don’t Know

[ ] Refused

8. Have you chewed gum, or used breath mints, lozenges, cough drops, or other cough or cold remedies in the last 8 hours?

[ ] Yes

[ ] No

[ ] Don’t Know

[ ] Refused

9. Have you used antacid, laxatives, or anti-diarrheal medications in the last 8 hours?

[ ] Yes

[ ] No

[ ] Don’t Know

[ ] Refused

10. Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours?

[ ] Yes

[ ] No

[ ] Don’t Know

[ ] Refused

11. Has a doctor ever told you that you had diabetes?

[ ] Yes

[ ] No

[ ] Don’t Know

[ ] Refused

- If the participant answers "Yes," go to question 12.

- If the participant answers "No" and is pregnant probe "*This includes gestational diabetes*." If the participant still answers "No" after probe, prepare to draw participant’s blood.

- If the participant is not pregnant and answers that she had gestational diabetes while pregnant, indicate that this does not include gestational diabetes and prepare to draw the participant’s blood.

- If the participant answers "No" and is not pregnant, prepare to draw the

participant’s blood.

12. Have you taken any insulin in the last 8 hours?

[ ] Yes

[ ] No

[ ] Don’t Know

[ ] Refused

• Record the participant’s response and prepare to draw the participant’s blood.

The entire standard operating procedure that includes the questions, venipuncture supplies, and venipuncture procedure appears [alink[05_NCS_AdultBlood_SOP.pdf|here]].

Follow a standard venipuncture protocol and collect blood in a 10 ml red-top vacutainer tube. Draw the blood with a stainless steel needle and use a pre-screened vacutainer tube.

An optimum amount of serum is 4 ml and the minimum is 0.5 ml.

For collection, loosen the tourniquet immediately after blood flow is established and release entirely as the last tube fills. Completely fill all the Vacutainer tubes and then withdraw the needle with a slow but firm motion. Red-top tubes should not be inverted or mixed. Label all tubes. Place the red-top tubes upright in a rack and allow them to clot at room temperature for 30 minutes. Centrifuge the red-top tubes for 10 minutes at the RPM necessary to attain a force of 1,000 x g. Using a transfer pipette, pipette the serum from each participant’s red-top tubes into the Wheaton Bottle and cap. Check to make sure that the numbers on the labels are the same. DO NOT ALLOW SERUM TO REMAIN IN CONTACT WITH THE CLOT FOR LONGER THAN 1 HOUR AFTER THE SPECIMEN IS COLLECTED. Mix the serum gently, cap each bottle and place upright in a -70° C freezer and store at the same temperature until shipment. The time between collecting blood and freezing serum should not be more than 1 1/2 hours. Note on the sample log if a sample is turbid or hemolyzed, or if the serum was left in contact with red cells for more than 1 hour or left at room temperature for more than 90 minutes before freezing.

The criteria for an unacceptable specimen are either a low volume (< 0.1 mL) or suspected contamination due to improper collection procedures or collection devices. In all such cases, request a second serum specimen. Contamination of specimen could occur from contact with indoor dust from improper handling.

The entire laboratory procedure is located

[alink[03_CDC_Lab_Procedures_PBDEs.pdf|here]].

Normal concentration range (ng/g lipid) of Brominated flame retardants (BFRs) in human serum appear in table below.

Compound	Median	Quartile Range	<Limit of Detection (LOD)
BDE-47	8.4	5.4-18	10%
BDE-100	1.7	1.0-3.5	6%
BDE-99	1.7	1.4-2.5	16%
BB-153	0.33	0.27-1.3	23%
BDE-154	0.21	0.21-0.28	71%
BDE-85	0.21	0.21-0.37	56%
BDE-153	2.2	1.2-3.8	3%
BDE-183	0.21	0.21-0.21	65%

Protocol source: https://www.phenxtoolkit.org/protocols/view/240201