



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.

Sample Collection Procedures

Supplies:

- Personal Protective Equipment (PPE) per Exposure Control Plan (e.g., gloves, lab coat, etc.)
- One pre-labeled, prescreened, sterile 120 ml urine collection container with screw-on lid
- Adult Urine Collection Instructions
- Biohazard transport bag, approx. 6" x 6"
- Absorbent pad, 100 ml
- Kim Wipe, 14.7" x 16.6"
- General trash bag
- Biohazard waste bag, approx. 19" x 24"
- Specimen collection tray
- Hand sanitizer
- Chux pads
- Biospecimen transport cooler with:
- Dry ice, a minimum of 2 pounds of dry ice is recommended
- Dry ice gloves

Review the adult urine collection procedures with the participant using the Adult Urine Collection Instructions and demonstration supplies.

- Emphasize to the participant how the cap of the collection container should be handled as the specimen is collected per the Adult Urine Collection Instructions.
1. If the participant does not refuse the collection, continue with the urine collection process.
- If the participant refuses the collection, indicate that this is fine, thank the participant for his/her time, and record the refusal and the reason.

- If the participant has a physical limitation that prevents him/her from providing a urine specimen, record "Physical limitation."
 - If participant becomes ill during the visit or has an emergency that requires termination of the visit, record "Participant ill/emergency."
 - If there was a language issue due to the participant's primary language not being English record, "Language issue."
 - If there was not a sufficient amount of time for the urine collection, record "No time."
 - If the participant was unable to urinate, record "Unable to urinate."
 - If the participant was uncomfortable with the collection procedures, record "Uncomfortable with collection procedures."
 - If the participant refused for a reason other than those listed, record "Other" and specify.
 - If the participant was unwilling to provide a reason, record "Refused."
 - If the participant does not know why he/she did not continue with the collection, record "Don't know."
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2. Read the urine collection questions to the participant and record the responses.

a. "When did you last urinate?"

Record date and time. If the participant refuses to answer the question, record "Refused." If the participant does not remember, record "Don't know."

b. "When was the last time you had anything to eat or drink?"

Record date and time. If the participant refuses to answer the question, record "Refused." If the participant does not remember, record "Don't know."

c. "How much of what you ate was beef, pork, tuna, or salmon?"

Read each of the choices (none, less than one-quarter of the meal, one-quarter to one-half of the meal, more than one-half but less than three-quarters of the meal, three-quarters or more, but not all of the meal, all of the meal) and record how much was eaten.

If the participant refuses to answer the question, record "Refused."

If the participant does not remember or does not know, record "Don't know."

d. "Do you take creatine supplements?"

If the participant asks, explain that creatine supplements are often taken by athletes wishing to gain muscle mass.

Record "Yes," "No," "Refused," or "Don't Know."

3. Locate the adult urine collection supplies.

4. Verify that the Specimen ID label is affixed to the side of the urine collection container and is readable and not damaged.

5. Give the pre-labeled, unopened urine collection container, a Kim Wipe, and the Adult Urine Collection Instructions to the participant. The participant may refer to the collection instructions when collecting the urine specimen.

6. While the participant is in the bathroom collecting the urine specimen, put on a lab coat, cleanse hands, and put on gloves.

7. Place the biospecimen collection tray on a flat surface laying a Chux Pad on top of the tray.

8. When the participant returns, thank the participant for providing the urine sample (or for trying if no sample was collected) and ask him/her to place the specimen on the biospecimen collection tray.

9. Check the lid of the urine collection container to make sure it is securely closed.

10. Record the status of the urine collection as either "Collected" or "Not collected." Any amount of urine in the collection cup is considered a collected sample.

11. If the urine was not collected, record the reason:

- If the participant has a physical limitation that prevents him/her from providing a urine specimen, record "Physical limitation."
- If participant becomes ill during the visit or has an emergency that requires termination of the visit, record "Participant ill/Emergency."
- If there were issues with the collection equipment, record "Collection supplies malfunctioned."
- If there was a language issue due to the participant's primary language being Spanish record, "Language issue, Spanish."
- If there was a language issue due to the participant's primary language being

other than Spanish record, "Language issue, non-Spanish."

- If the participant has a cognitive disability that prevents him/her from understanding the instructions, record "Cognitive disability."
- If there was not a sufficient amount of time for the urine collection, record "No time."
- If the urine specimen was not collected for a reason other than those listed, record "Other" and specify.
- If the urine specimen was not collected because the participant refused, record "Refused."
- If the reason the urine specimen was not collected was unknown, record "Don't know."

12. Record the Specimen ID number on the urine collection container.

13. Place the urine specimen in the biohazard transport bag with the absorbent pad and seal the bag.

14. Put on the dry ice glove to place the sealed bag with the collection container upright on dry ice in the transport cooler. Be sure to refer to local Hazard Communication Plan for proper handling of dry ice.

15. Record the date and time the urine specimen was collected in the collection log.

16. Record where the urine collection occurred: in the participant's home, at a clinic, at a hospital, or other location and specify.

17. Record any comments, problems, or concerns pertaining to the urine specimen collection.

Samples should be refrigerated as soon as possible. Preferably, the specimen should be transferred to specimen vials within 4 hours of collection. If at all possible, at least five milliliters of urine is collected, and can be stored frozen in polypropylene vials or specimen cups. Crimped caps with rubber stoppers should not be used because they may contain 4-tert-Octylphenol (tOP). The specimens are then labeled, frozen, and stored on dry ice for shipping. All samples should be stored frozen until analysis. The entire urine collection procedure is available [alink[04_NCS_AdultUrine_SOP.pdf|here]].

Analyses is by on line SPE-HPLC-Isotope dilution-MS/MS.

The complete laboratory procedure is available [alink[01_2013_NHANES_Phenols_and_Parabens.pdf|here]].

The NHANES laboratory measures the following phenols and parabens in the urine sample.

Variable Name	SAS Label and SI Units
URXBPA	Urinary Bisphenol A (ng/mL)
URXBP3	Urinary Benzophenone-3 (ng/mL)
URXTRS	Urinary Triclosan (ng/mL)
URXBUP	Urinary Butyl paraben (ng/ml)
URXEPB	Urinary Ethyl paraben (ng/ml)
URXMPB	Urinary Methyl paraben (ng/ml)
URXPPB	Urinary Propyl paraben (ng/ml)
URXTLC	Urinary Triclocarban (ng/mL)
URXDCB	2,4-Dichlorophenol
URX14D	2,5-Dichlorophenol

2009-2010 NHANES geometric mean (in µg/L) for all age groups 6 and older

Bisphenol A 1.83

Benzophenone-3 22.3

Triclosan 14.5

Butyl paraben < LOD

Ethyl paraben < LOD

Methyl paraben 57.1

Propyl paraben 6.97

Means for triclocarban, 2,4-Dichlorophenol, and 2,5-Dichlorophenol are not

available, those analytes were measured in later NHANES.

Protocol source: <https://www.phenxtoolkit.org/protocols/view/240301>