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 2007-2008 protocol.

The full National Health and Nutrition Examination Survey 2007-2008 Oral Glucose Tolerance Test Procedures can be found here: 2007-2008 NHANES Oral Glucose Tolerance Test Manual.

Exclusion Criteria:

Persons will be **excluded** from this component if they:

• Report that they are taking oral medications for diabetes;

• Report that they are taking insulin;

• Report that they are pregnant;

• Report that they have hemophilia;

• Report that they have received cancer chemotherapy in the last 3 weeks; and

• Report that they have not fasted at least 9 hours.

SP = Sample Person.

1. Did you eat or drink anything other than plain water after [Insert time at 9 hours prior to sample collection] last night?

[ ] Yes

[ ] No

[ ] Refused

[ ] Don't Know

If the answer is "No," then he or she **has met** the 9-hour fast. If the answer is "Yes," "Don't know," or "Refused," then the actual fasting time is unknown. The SP is **excluded** from the Oral Glucose Tolerance Test if the 9-hour fast is not met and will not be met with 1 hour and 40 minutes left in the session.

Confirmation Question:

2. Have you had any of the following since {insert time from 1 here}?

Coffee or tea with cream and sugar? [Include milk or non-dairy creamers.]

[ ] Yes If Yes, record time and date _____

[ ] No

Alcohol, such as beer, wine, or liquor?

[ ] Yes If Yes, record time and date _____

[ ] No

Gum, breath mints, lozenges, or cough drops, or other cough or cold remedies?

[ ] Yes If Yes, record time and date _____

[ ] No

Antacids, laxatives, or anti-diarrheals?

[ ] Yes If Yes, record time and date _____

[ ] No

Dietary Supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.]

[ ] Yes If Yes, record time and date _____

[ ] No

3. Are you currently pregnant?

1 [ ] Yes

2 [ ] No

3 [ ] Don't Know

If the answer is "Yes," then the SP is blocked from the Oral Glucose Tolerance Test.

If the answer is "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.

4. {Is SP/Are you} now taking insulin?

1 [ ] Yes

2 [ ] No

7 [ ] Refused

9 [ ] Don’t Know

If the SP answers "Yes," the SP is excluded from the Oral Glucose Tolerance Test.

If the answer is "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.

5. {Is SP/Are you} now taking diabetic pills to lower {his/her}/your} blood sugar? These are sometimes called oral agents or oral hypoglycemic agents.

1 [ ] Yes

2 [ ] No

7 [ ] Refused

9 [ ] Don’t Know

If the SP answers "Yes," the SP is excluded from the Oral Glucose Tolerance Test.

If the SP answers "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.

6. Do you have hemophilia?

1 [ ] Yes

2 [ ] No

7 [ ] Refused

9 [ ] Don’t Know

If the SP answers "Yes," the SP is excluded from the Oral Glucose Tolerance Test.

If the SP answers "No" or "Don’t Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.

7. 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 [ ] Don't Know

If the SP answers "Yes," the SP is excluded from the Oral Glucose Tolerance Test.

If the SP answers "No" or "Don't Know," the SP drinks the Trutol® and receives the venipuncture for the Oral Glucose Tolerance Test.

First Venipuncture

A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast.

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.

Editor's 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. 2007-2008 NHANES 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.

Administering the Trutol® (Dextrose Solution)

SPs who weigh more than 100 pounds will drink 10 ounces of Trutol®. SPs who weigh less than 94 pounds must have a calibrated dose of Trutol®.

Body Weight		**75 g Concentration**	
lb.	**kg**	**oz.**	**mL**

94+	42.7+	10.0	295
90-93	40.9	9.5	283
85-89	38.6	9.0	267
80-84	36.4	8.5	251
75-79	34.1	8.0	235
70-74	31.8	7.4	220
65-69	29.5	6.9	204
60-64	27.3	6.4	188

Note: The investigator should record the calibrated amount of Trutol® given to the sample person.

Ask the SP to indicate a preference for one of the three flavors. Choose the flavor that matches the preference of the soft drink flavor that he or she prefers. Follow the instructions; remove the correct amount of Trutol® from the bottle before handing the bottle to the SP. Use a small medicine cup to measure the correct amount to remove and discard the excess Trutol®. Hand the SP a cold bottle of Trutol® (containing the calibrated dose) and a straw. SPs MUST consume the entire calibrated dose of the Trutol within 10 minutes.

Recite the script "Please drink this solution within 10 minutes" and start the timer. The timer counts down from 10:00 minutes.

When the SP has finished drinking the entire calibrated dose of Trutol®, or cannot continue drinking the Trutol, then stop the timer.

The choices for the amount of solution that the SP consumed are "All," "Some," or "None."

Record the amount of solution the SP drank. If the SP drank "some" or "none" of the Trutol® solution, then the section status is Not Done.

If the total time is 00:10:00, then "Solution not consumed in 10 minutes."

Second Venipuncture

If an SP consumed the entire calibrated dose of the Trutol® solution in 10 minutes, then he or she is eligible to have a 2 ml gray-top tube drawn 2 hours, -20 or +15 minutes, after he or she finished consuming the Trutol®. (He or she must maintain the fast until the second blood draw is completed.)

Editor's 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. 2007-2008 NHANES Lab Manual

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 Samples for the Plasma Glucose Test

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. [alink[NHANES_Lab_manual.pdf|2007-2008 NHANES Lab Manual]]

Centrifuge and separate the plasma from the tube as soon as possible. Process the specimen even if the contents of the gray-top tube clot.

• Separate the plasma by centrifugation.

• Use a calibrated plastic transfer pipette to transfer at least 0.5 mL plasma.

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

• Close all vessels securely to prevent leakage and evaporation.

Laboratory Assay for Plasma Glucose

The Diabetes Working Group recommends that glucose concentration be determined according to a hexokinase-mediated reaction such as the one developed by the University of Minnesota for use in the National Health and Nutrition Examination Survey: 2007-2008 NHANES Oral Glucose Tolerance Test Lab Assay

To aid comparability, the Diabetes Working Group recommends that the investigator record the make and manufacturer of equipment used and the repeatability and coefficients of variation for the assay.

Reference Ranges:

Non-fasting glucose concentration normally ranges between 60-139 mg/dL

Fasting plasma glucose concentration normally ranges between 60-100 mg/dL

Trutol® a registered trademark, Thermo Fisher Scientific Inc.

Protocol source: https://www.phenxtoolkit.org/protocols/view/141001