

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 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 answer is "No," then he or she **has met** the 9-hour fast. If answer is "Yes," "Don't know," or "Refused," then the actual fasting time is unknown.

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 answer is "Yes," then the SP is blocked from the Fasting Plasma Glucose test. If answer is "No" or "Don't Know," the SP completes Fasting Plasma Glucose 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 Fasting Plasma Glucose test. If answer is "No" or "Don't Know," the SP completes Fasting Plasma Glucose 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 Fasting Plasma Glucose test. If the SP answers "No" or "Don't Know," the SP completes Fasting Plasma Glucose test.
6. Do you have hemophilia? (exclusion from Phlebotomy)
1 [] Yes
2 [] No
7 [] Refused
9 [] Don't Know
If the SP answers, "Yes," the SP is excluded from the Fasting Plasma Glucose test. If the SP answers "No" or "Don't Know," the SP completes Fasting Plasma Glucose test.
7. Have you received cancer chemotherapy in the past 4 weeks or do you anticipate such therapy in the next 4 weeks? (exclusion from Phlebotomy)
1 [] Yes
2 [] No
7 [] Refused
9 [] Don't Know
If the SP answers "Yes," the SP is excluded from the Fasting Plasma Glucose test. If the SP answers "No" or "Don't Know," the SP completes Fasting Plasma Glucose

test.

Using the Glucometer

There are many types of glucose meters available that are appropriate for this protocol. Follow manufacturer's recommendations for a finger stick (or other site), calibration, and measurement.

Reference Ranges:

Fasting plasma glucose concentration between 60-100 mg/dL

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

Protocol source: https://www.phenxtoolkit.org/protocols/view/140802