

## Data Collection Worksheet

**Please Note:** The Data Collection Worksheet (DCW) is a tool to aid investigators to integrate the collection of PhenX measures in your study. The PhenX measures that you selected and added to your Cart are presented in the DCW in alphabetical order. The DCW includes worksheets for data collection. Variables derived from the collected data are shown in the Data Dictionary (DD) with variable names and unique PhenX variable identifiers. The collection of DCWs produced by the Toolkit is not designed as a data collection instrument. Each investigator will decide how to integrate PhenX measures into data collection for their study.

### 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 11:30 last night?

Yes -> Exclude (Reason: 9-hour fast is not met).

No -> Continue

Refused -> Continue

Don't Know -> Continue

### ALTERNATIVE:

When did you last have anything except water to eat or drink?

Date: \_\_/\_\_/\_\_      Time: \_\_:\_\_ AM or PM

Confirmation Question:

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

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

Yes If Yes, record time and date\_\_\_\_\_

No

2.2. Alcohol, such as beer, wine, or liquor?

Yes If Yes, record time and date\_\_\_\_\_

No

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

Yes If Yes, record time and date\_\_\_\_\_

No

2.4. Antacids, laxatives, or anti-diarrheals?

Yes If Yes, record time and date\_\_\_\_\_

No

2.5. 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 ->Exclude (Reason: Pregnant)

2  No -> Continue

3  Don't Know -> Continue

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

1  Yes ->Exclude (Reason: Insulin)

2  No -> Continue

7  Refused -> Continue

9  Don't Know -> Continue

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 ->Exclude (Reason: Diabetic Pills)

2  No -> Continue

7  Refused -> Continue

9  Don't Know -> Continue

6. Do you have hemophilia? (exclusion from Phlebotomy)

1  Yes ->Exclude (Reason: Diabetic Pills)

2  No -> Continue

7  Refused -> Continue

9  Don't Know -> Continue

7. Have you received cancer chemotherapy in the past four weeks or do you anticipate such therapy in the next four weeks? (exclusion from Phlebotomy)

1  Yes ->Exclude (Reason: Diabetic Pills)

2  No -> Continue

7  Refused -> Continue

9  Don't Know -> Continue

*Note from the Diabetes Working Group: The investigator should record the reason(s) a sample person is excluded from the test.*

8. Exclusion Criteria:

Please mark reason for exclusion

Taking oral medications for diabetes

Taking insulin

Pregnant

Hemophilia

Received cancer chemotherapy in the last 3 weeks

Has not fasted at least 9 hours.

None - proceed with blood draw

9. Make and manufacturer of the glucometer used:

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10. Repeatability of the assay: \_\_\_\_\_

11. Coefficient of variation for the assay: \_\_\_\_\_

12. Glucose concentration: \_\_\_\_\_ (mg/dL)

13. Was the participant fasting?

Yes

No

### **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#Source>