

### **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.

#### **Urine Collection**

Editor's Note: Please review chapter 5 of the Laboratory Procedures Manual from the National Health and Nutrition Examination Survey 2007-2008 for a full description of urine collection and processing procedures: 2007-2008 NHANES Lab Manual.

The coordinator explains the following instructions to the subject before urine collection:

- · Wash hands with soap and water;
- It is important that the cup and cap not touch or come into contact with any parts of the body, clothing, or external surfaces; and
- Close container to minimize exposure to air.

Refrigerate all insufficient urine samples. When additional urine is obtained, pool the urine, mix, and process.

## **Record the Results of Urine Specimen Collection**

Note whether or not urine was collected, and note whether the volume of urine was sufficient or required a second specimen.

Note whether blood is present/visible in the specimen.

## Process the Urine for the Urinary Albumin Assay

Pour 3 mL of the specimen for urine albumin into a 5 mL vessel.

# Laboratory Procedure for Urinary Albumin

The Diabetes Working Group (WG) recommends that urine albumin concentration be determined according to a fluorescent immunoassay such as the one developed by the University of Minnesota for use in the National Health and Nutrition Examination Survey: <u>Urinary Albumin Lab Assay</u>.

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

#### **REFERENCE RANGES**

(From the NHANES/University of Minnesota laboratory protocol)

Urinary Albumin in Healthy Subjects					
Number of Subjects	Author	Method	mg/L µg/mL	µg/min	mg/24 h
100 adults	Chavers et al. (1994)	FIA	0.2-17.3*	0.8-14.6	1.1-21.0
20 adults	Mogenson (1976)	RIA		5-20	3.6-23.0
11 adults	Howey et al. (1987)	RIA	8.13+	7.1**,+	10.2+
20 children	Fielding et al. (1983)	ELISA		1.2-15.9**	1.7-22.9
NHANES III	Jones et al. (2002)	FIA	< 30		

 $<sup>^{\</sup>ast}$  obtained from subject data in the published manuscript.  $^{\ast\ast}$  calculated from published units. + mean values.

Protocol source: <a href="https://www.phenxtoolkit.org/protocols/view/141501">https://www.phenxtoolkit.org/protocols/view/141501</a>