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.

1. Specimen Collection, Storage, and Handling Procedures; Criteria for Specimen Rejection

A. Urine specimen should be collected in a urine specimen container that is sterile and prescreened for trace sodium contamination. Sodium is stable frozen indefinitely with multiple freeze-thaw cycles and for 45 days at room temperature. Bacterial growth must be avoided.

B. Ensuring 24-hour collection is essential. Sodium excretion varies during a 24-hour time period, so over-collection and under-collection must be avoided. Completeness of collection is assessed through self-reporting, total urine volume, normalization to urinary creatinine, or oral para-amino benzoic acid (PABA) administration and recovery. PABA can be administered prior to urine collection to ensure completeness of collection, as 93% of the dose is recovered in urine within 5 hours of administration. The use of PABA to assess completeness of the urine collection is not recommended for field studies. It requires that each participant take a PABA pill three days prior to the start of collection thereby increasing the risks of non-compliance and attrition. In addition, laboratory facilities for the testing of PABA in the urine are limited and where they exist, will increase the costs of the study.

C. Sodium and potassium content in the urine may be determined through Ion Selective Electrode. Creatinine content may be determined through the Creatinine (urinary) Jaffe kinetic method.

D. Aside from sodium intake, urinary sodium excretion can be modified by potassium intake, physical activity, climate, chronic disease, hypertension, and renal function.