



INSTRUCTIONS FOR 24-HOUR URINE COLLECTION

Form # 37A

Supplies:

Gallon jugs (no preservative) and label (patient name/ID#, start/stop date/time)
Large ziplock bags for gallon jug storage
Collection "hat" or urinal
Funnel Cooler with handle for transporting sample
Ice packs for transporting sample
Written instructions

Preparation/Day One :

One-gallon sample collection containers (containing **no** preservative) will be used. Patients will be given necessary supplies, written instructions and verbal instructions. Emphasize the importance of complete collections. Drink the *usual* amount of liquid. Sample collection should start in the morning
First morning void: discard first void, but record the time and date on the container.

Sample Collection:

Collect every bit of urine for the next 24 hours.
Collect urine in the "hat" or urinal provided, then carefully transfer all contents into the larger collection container.
If you are going to have a bowel movement, first collect all urine so that none is lost. (Do not collect stool.)
After carefully transferring urine into the larger collection container, close the container securely and store upright.
Wash the "hat" or urinal and allow it to dry completely before next use.
Participants may wish to use various reminder techniques so they do not forget to collect their urine (note on the toilet seat, string around a finger, safety pin on clothing).

Sample Storage:

Keep the collection container in a zip lock bag marked "biohazard."
Store the sample in a refrigerator during the entire collection period and after.
If refrigeration is not available, store the sample in a cooler with ice packs.
If no cooler/ice packs are available, store sample in a cool dark place.
Do not expose sample to extreme temperatures. Avoid freezing.
Always store the sample upright to avoid leakage.
Keep the sample refrigerated at all times during collection and after.

Completion/Day Two:

On day two, collect all urine up to the same time you started the day before.
Include the first a.m. void on day two and try to void at the end of collection.
Record the time and date of the last void on the container.
Do *not* stop collecting before this time. Do *not* collect urine after this time.
Bring the sample to the PCC (in a cooler with ice packs if possible).
Coordinator completes Form 37, 24-hour urine checklist.

Samples will be collected in a GCRC if possible. If no GCRC is available, the participant will be instructed per the guidelines above as an outpatient. If there is no GCRC and the participant is flying to the PCC, the study will pay for a hotel room the night before the visit to ensure that the participant is able to collect and transport the sample.

Clinic visits are to occur in the morning at baseline, F5 and annually. Starting the 24-hour urine collection at the time of the first morning void (discard urine but record the time) is ideal, but not essential. It is okay to start anytime as long as urine is collected over 24 hours. Sites will develop their own methods/materials for patient training based on these guidelines.



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Acceptability of 24-Hour Urine Samples:

1. Mechanics of Collection:

Whenever a 24-hour urine sample is collected, the coordinator will complete 24-Hour Urine Checklist Form 37 (which is to be kept in the research chart but not data-entered). Based on this information, the PI will determine whether or not the sample is acceptable in terms of the mechanics of collection.

- a. If the PI determines that the sample is *acceptable* based on the mechanics of collection, urine will be aliquotted and sent to the central lab and repository.
- b. If the PI determines that the sample is *unacceptable* based on the mechanics of collection (sample is not refrigerated or is exposed to extreme temperatures, collection time is <20 hours or >28 hours, start/stop time cannot be determined, >1/2 cup of specimen is lost, spilled or leaks from container, anything unusual that renders the sample unacceptable in the PI's opinion):
 - i. The PI may ask the participant to repeat the sample collection *before* the start of blinded medication. This is *not* required by the study.
 - ii. If the PI determines that a sample is completely lost or so inadequate as to be effectively lost, and is not repeated, missing data codes will be entered on Urine Sample Collection Form 16.

Note: Whether an inadequate sample is repeated or not, the participant should continue to collect urine at all subsequent visits.

2. Adequacy of Sample for Data Analysis (does not directly concern the coordinator):

Provided that proper collection procedures are maintained (mechanical aspects per Form 37), 24-hour urine samples will be considered valid (complete) if creatinine excretion is within 75-125% of that predicted using Walser formulas, based on actual body weight. PIs are to review outliers of their own subjects and adjudicate if samples are acceptable based on extremes of body size. The Quality Control Subcommittee must review and concur with PI recommendations in order to include samples in analysis of creatinine excretion, although urine aldosterone/creatinine ratios of incomplete collections will be included in the analysis. Judgments will be made on the basis of dietary status (vegan or vegetarian), creatinine excretion, body weight and BMI. The Quality Control Subcommittee will develop specific criteria for adjudication. Note that if a sample is determined incomplete, even at baseline, participants will continue to collect 24-hour urine at all subsequent visits.