# CHRONIC RENAL INSUFFICIENCY COHORT (CRIC) STUDY

## Manual of Procedures Version 2 dated August 2007
## Addendum #2
## DATED: January 2008

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**Regarding the processing of urine proteomics specimens, the below text is intended to clarify a mistake that was brought to our attention in the current MOP, Version 2.0. The text below provides clarification of the MOP instructions regarding collection and processing of proteomics specimens as previously specified in the Urine Proteomics Protocol, Version 1 dated 9/16/05. If your site is not currently following the corrected instructions below, please implement this process immediately. In addition, the corrected text/instructions, as outlined below, will be incorporated into the CRIC MOP upon finalization of additional pending changes.**

## CRIC MOP Version 2.0 currently reads:

***(PROTRANS) - Proteomics Specimen Transfer:***

**Purpose:** This case report form records Proteomics specimen status during collection at the site and transfer to the Central Laboratory.

**Who:** Completed by the Research Coordinator.

**When:** This case report form is completed at:
Baseline visit (Visit 3)
12-month clinic visit (Visit 5)
24-month clinic visit (Visit 7)
36-month clinic visit (Visit 9)
48-month clinic visit (Visit 11)
60-month clinic visit (Visit 13)

**Directions:** Additional information is available in the Proteomics protocol in Appendix J of this Manual of Procedures.

A 90 ml clean catch urine specimen is collected from participants at the baseline visit (Visit 3) and each annual clinic visit thereafter.

Urine specimens may be collected over 2 time periods on a given day for a visit and processed as combined specimen if the participant experiences problems voiding the amount required.

Proteomics specimen should be collected prior to GFR testing.

***PROTRANS*** is entered and verified in the Data Management System.

## Updated text will read:

***(PROTRANS) - Proteomics Specimen Transfer:***

**Purpose:** This case report form records Proteomics specimen status during collection at the site and transfer to the Central Laboratory.

**Who:** Completed by the Research Coordinator.

**When:** This case report form is completed at:
Baseline visit (Visit 3)
12-month clinic visit (Visit 5)
24-month clinic visit (Visit 7)

36-month clinic visit (Visit 9)
48-month clinic visit (Visit 11)
60-month clinic visit (Visit 13)

**Directions:** A 90 ml clean catch urine specimen is collected from participants at the baseline visit (Visit 3) and each annual clinic visit thereafter.

Urine specimens may be collected over 2 time periods on a given day for a visit and processed as separate specimens if the participant experiences problems voiding the amount required. The collection date and time for the initial specimen should be recorded.

Proteomics specimen should be collected prior to GFR testing.

***PROTRANS*** is entered and verified in the Data Management System.

## CRIC MOP Version 2.0 currently reads:

**10.C.4. "Clean-Catch" Urine Proteomics Sample Collection**

Encourage participants to stay hydrated even while fasting for the visit. However, do not collect samples after acute fluid load (>24 ounces) or after participant exertion. Collection will be random and, therefore, considered a "spot" urine collection. Participants who have difficulty producing a urine specimen may be offered a glass of water, and subsequent urine specimens may be collected later in the visit to bring the volume up to the required amount. This sample is being collected for future studies and will be processed for storage shortly after collection. The sample volume collected should be 100 mls. If a participant cannot void 100 ml at once, it is permissible to store the sample in the refrigerator and to ask them to void again. The volume from the second void can be combined with the first sample. If fluid intake is not restricted, a participant should drink water. If the combined total volume is less than 100 ml, the available sample should be processed and sent to the lab.

If the sample is being collected prior to the GFR test, it must be collected before the Glofil injection is given. This sample should not be collected during the course of collecting urine for the I-GFR test. Please note that inability to provide this sample does not preclude a participant from continuation in the CRIC Study.

## Updated text will read:

**10.C.4. "Clean-Catch" Urine Proteomics Sample Collection**

Encourage participants to stay hydrated even while fasting for the visit. However, do not collect samples after acute fluid load (>24 ounces) or after participant exertion. Collection will be random and, therefore, considered a "spot" urine collection. Participants who have difficulty producing a urine specimen may be offered a glass of water, and subsequent urine specimens may be collected later in the visit to bring the volume up to the required amount. This sample is being collected for future studies and will be processed for storage shortly after collection. The sample volume collected should be 90 mls. If a participant cannot void 90 ml at once, it is permissible to obtain a second sample. Each sample should be processed separately as described in section 10.D.2. If fluid intake is not restricted, a participant

should drink water. If the total volume obtained is less than 90 ml, the available samples should be processed and sent to the lab.

If the sample is being collected prior to the GFR test, it must be collected before the Glofil injection is given. This sample should not be collected during the course of collecting urine for the I-GFR test. Please note that inability to provide this sample does not preclude a participant from continuation in the CRIC Study.

## CRIC MOP Version 2.0 currently reads:

### 10.D.2. Sample Processing for Urine Proteomics

Instruct each participant to collect a midstream urine sample in a urine specimen collection container. This specimen should be collected following the "clean-catch" instructions. The sample collected should be a minimum of 50 mL.

- Pour spot urine collection into the two 50ml conical vials and centrifuge at 2400rpm for 20 minutes
- Using a pipet, transfer the supernatants to the 10 aliquot tubes provided. Fill each tube to the 9mL mark. Be careful not to disrupt any cellular debris at the bottom of the tube. Any remaining urine can be discarded.
- For minimum urine collection, at least 50mL must be obtained. Then fill six of the ten 10 mL cryovials to the 9mL mark.
- Store the samples in the upright position. Immediately freeze the tubes at -80 C (if -80 C is not available freeze at -20 C).

## Updated text will read:

### 10.D.2. Sample Processing for Urine Proteomics

Instruct each participant to collect a midstream urine sample in a urine specimen collection container. The specimen should be collected following the "clean-catch" instructions. The sample collected should be a minimum of 90 mL.

- Place the urine sample on ice immediately after it is collected.
- Within one hour of collection, divide the sample equally among the conical tubes provided and centrifuge in a refrigerated centrifuge for 5 minutes at 2000 g.
- Using a pipet, transfer the supernatants to the 10 aliquot tubes provided. Fill each tube to the 9mL mark. Be careful not to disrupt any cellular debris at the bottom of the tube. Any remaining urine can be discarded.
- Freeze the 10 tubes at -80 C (if -80 C is not available freeze at -20 C).
- Ship samples to the central lab on dry ice on a monthly basis with all of the other TRANS DRY samples.