

SOF Visit 4
Urine protocol update
10.12.93

This SOF urine specimen protocol should be implemented as soon as possible for all remaining SOF participants. This protocol supersedes collection instructions outlined in version 4.2.

Prior to the visit

1. Mail a 30 ml labeled urine container and ziploc bag to the participant along with the self-administered questionnaire.

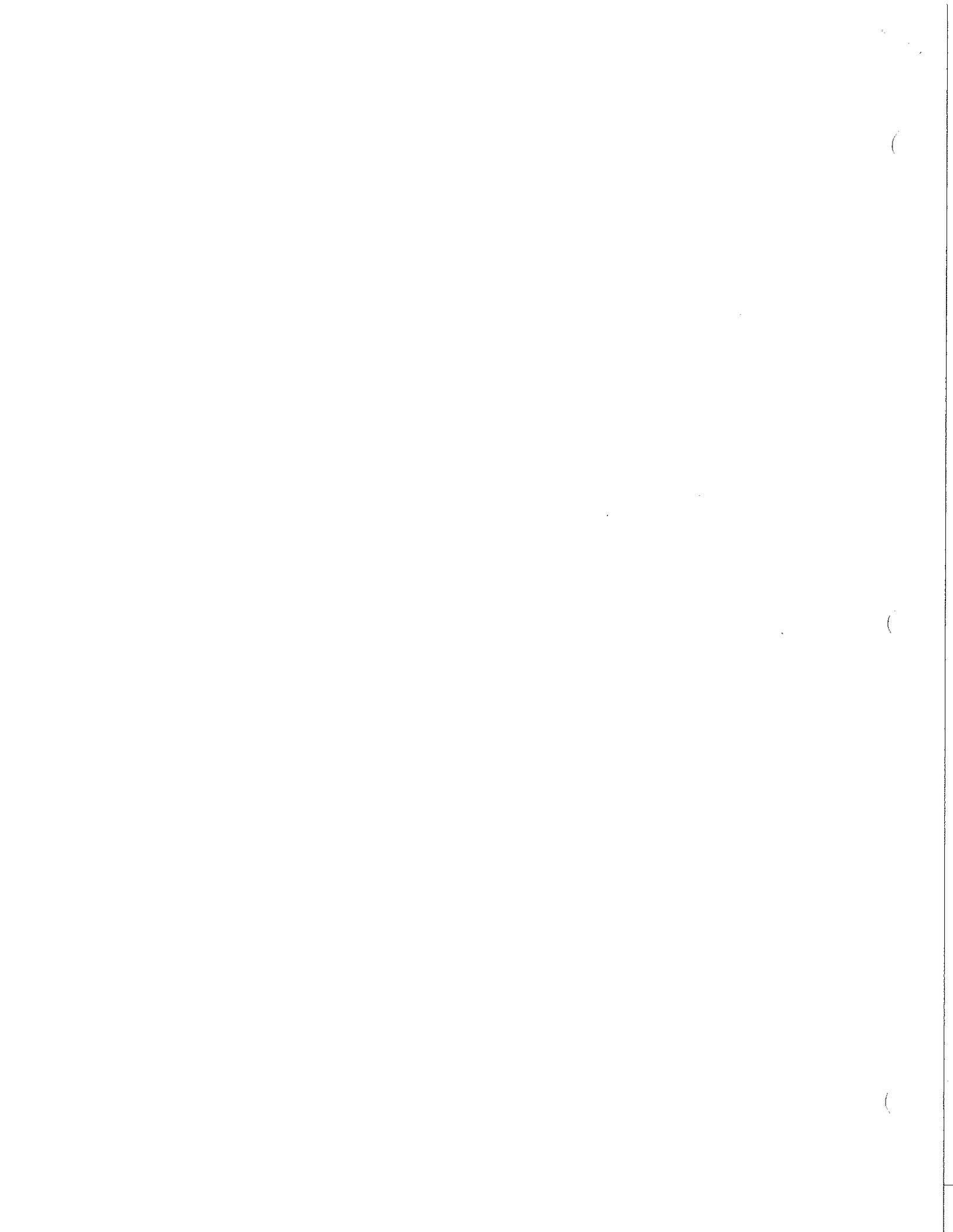
The following written instructions are attached to the container when sent to participants:

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- Please bring a urine sample with you to the clinic. The sample should be collected in the enclosed container and placed in the ziploc bag on the morning of your clinic visit.
 - Collect the sample when you first urinate in the morning AFTER about 5AM.
 - Please urinate directly into the container. Fill the container about 2/3 full. If you are unable to use the container provided, use a clean glass jar and then transfer the urine specimen to the container.
 - Write the time you collected the sample on the container and place the container inside the ziploc bag. Then put the container in the refrigerator or on ice until you leave for the clinic.

2. Another reminder to obtain a urine sample should be included with any other instructions for fasting and other preparations for the clinic visit.

3. During the reminder phone call prior to the clinic visit, the participant is again asked to bring a urine sample with her to the clinic. At that time, she is asked if she has any questions about the procedures to follow, and these are briefly reviewed with her.

4. If a participant does not bring a urine sample, a sample will be collected at the clinic. The time the sample is collected and the number of the void should be recorded.



STUDY OF OSTEOPOROTIC FRACTURES (V4)

Protocol for Urine Specimens

1. Introduction

The purpose of urine samples is to identify women who lose bone most rapidly. The amount of calcium in the urine may be a measure of the rate of bone loss. Other markers of bone loss are being developed; we will preserve the samples for several years until the best potential markers have been developed.

2. Equipment

- Urine hats: "American Specipan" from Baxter Hospital Supply, catalogue # 134465. Hats are not required since we are just doing a spot urine but if you want to use them you can.
- Plastic urine containers (clean catch containers used in FIT are fine).
- 4 ml tubes for storage and shipping.
- Color cap inserts (green) for the cryotubes containing urine.

3. Preparation of participants

We will be doing "spot" urines - just a regular collection of urine from the participants that does not require a prolonged collection. When scheduling the fourth visit, inform all participants that we will be collecting a urine specimen and we'd like to get the first or second void. Some participants may feel more comfortable and they may have an easier time providing a specimen if they can collect it at home. This is fine. On the day of her clinic visit, the participant should collect the specimen at home and keep it refrigerated until she comes in for her visit. When the participant comes to the clinic, her specimen should be dealt with as quickly as possible so that it gets frozen within as close to the allotted time frame as possible.

If the participant prefers to provide the specimen while at the clinic, inform her that, if possible, we'd like to get either a first or second void, hence she should plan on providing a specimen on arrival to the clinic if possible (hopefully this would be the first or second void, however for some women it will still probably be more than the second void). Since morning participants for SOF will be coming in without eating, whenever possible, try to collect the urine before the Ca45 meal. If a participant is unable to provide a first or second void, still collect the specimen. Be sure to record what number void the specimen is on the urine exam form.

4. Collecting the specimen

Inform the participant that we are collecting a urine specimen and would prefer the first or second voided specimen, if possible. Urine collected after the second void, even if collected during the afternoon, will still be stored and analyzed.

Urine will be either collected in "urine hats" set in the toilet or in clean catch containers as used in FIT. If hats are used, a staff member should place the hat in the toilet and the participant should go to the bathroom and empty her bladder into the hat. She does not need to clean her urethra. It does not matter if some of the urine spills into the toilet.

After the participant has voided, a staff member retrieves the hat and stores the urine in a plastic urine container.

5. Measuring, freezing and shipping the urine specimen

To prevent bacterial overgrowth and the breakdown of substances we would like to measure, the urine must be processed within one hour of collection.

Take a 4 ml sample for storage in the cryotube. Pipette about 3.6 ml of urine into 4 ml cryotubes (same as used for serum) and fill them in the same way as the serum, leaving at least 10% unfilled to prevent breaking the tubes during freezing. Use a green cap insert to mark the urine tube.

The urine sample in the cryotube should be frozen at -20° C as soon as possible (within 1 hour of collection) The urine tubes should be labelled, stored at -20° C, just as you do with serum, and shipped with regular shipments to BRI. Altogether, not including the samples for the calcium 45, each participant will have two tubes to be shipped to BRI: one serum (collected at the same time as the blood for Ca45) and one urine.

We are not using preservatives in the urine (to prevent growth of bacteria) because we will freeze it within 1 hour of collection. The urine needs no special treatment or preservation for the measurements we plan.