

Biospecimen Adult Urine Procedures

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Biospecimen Adult Urine Procedures

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Biospecimen Adult Urine Procedures

1.0 Overview

Adult spot urine specimens will be collected from women at the pre-pregnancy visit, pregnant women at two pre-birth visits and the birth visit¹, and from the primary caregiver at the 6-, 12-, 36-, and 60-month visits. Once collected, a Regional Operations Center (ROC) data collector will transport the urine specimen on dry ice to the Sample Handling Location (SHL) where the urine specimen will be receipted and stored frozen until shipped to the National Children's Study (NCS) Repository. In the future, these biospecimens will be analyzed to obtain information about physiological conditions and environmental exposures.

1.1 Requirements/Conditions for Collection

The participant must have provided all appropriate consents and authorizations granting permission for collection of biospecimens as indicated in the NCS Informed Consent Manual of Operations.

Adult urine collections except for the birth visit will occur during the respective study visit in either a home or clinic setting. A participant may provide a urine specimen at any time during a study visit.

1.2 Pre-Visit Preparation

Prior to the study visit, ROC staff will:

- Ensure that all materials and supplies are prepared and organized in advance of the study visit. A list of equipment and supplies for collection and transport is provided in a following section. For details on manufacturer and part numbers of equipment and supplies, refer to the Biospecimen Overview of Activities.

¹Additional details on the adult urine collection at the birth visit can be found in the Birth Procedures

- The urine specimen will be transported in a cooler on dry ice until stored at the SHL.
 - Ensure that sufficient dry ice is available to freeze the urine specimen and maintain it in a frozen state until it is placed in storage.
 - ROCs will need to take into account local transport conditions, but a minimum of 2 pounds of dry ice is recommended for frozen urine transport.
- Print the Adult Urine Collection Instructions to provide to participants during the study visit.
- Ensure eye-readable, 2-D barcoded Specimen ID labels are affixed to the urine specimen collection container per NCS specifications.
 - Refer to the Biospecimen Overview of Activities for more detailed information on labeling procedures and specifications.

2.0 Collection and Transport Procedures for Adult Urine

These procedures assume that the urine collection process and the recording of information about the participant are conducted in such a way that the participant is comfortable and there is little or no delay in recording information as soon as a response is provided or an activity is completed. Information should be recorded in the Adult Urine Instrument provided by the ROC Information Management System (IMS) Hub.

Always use standard precautions when handling biospecimens. Refer to local ROC Exposure Control Plan. All supplies used can be discarded in the general trash unless they are visibly contaminated with blood in which case they should be placed into a biohazard waste bag for disposal.

2.1 Collection and Transport Equipment and Supplies

- Personal Protective Equipment (PPE) per local ROC Exposure Control Plan (e.g., gloves, lab coat, etc.)
- One pre-labeled, prescreened, sterile 120 ml urine collection container with screw-on lid
- One urine collection container labeled “Demo” to use for demonstration purposes.

- Adult Urine Collection Instructions
- Biohazard transport bag, approx. 6"x6"
- Absorbent pad, 100 ml
- Kim Wipe, 14.7" x 16. 6"
- General trash bag
- Biohazard waste bag, approx. 19" x 24"
- Specimen collection tray
- Hand sanitizer
- Chux pads
- Biospecimen transport cooler with:
 - Dry ice, a minimum of 2 pounds of dry ice is recommended
 - Dry ice gloves
- Computer with bar code scanner that includes automated system for electronic data capture
- Adult Urine Instrument – developed by the ROC IMS Hub according to the Adult Urine Collection Instrument Specifications
 - Hard copy paper and pencil instrument (PAPI) back up forms are available on the NCS portal for collection of instrument data if an electronic data capture system is unavailable at an NCS visit.

2.2 Procedures for Adult Urine Collection and Transport

1. Review the adult urine collection procedures with the participant using the Adult Urine Collection Instructions and demonstration supplies.
 - Emphasize to the participant how the cap of the collection container should be handled as the specimen is collected per the Adult Urine Collection Instructions.
2. If the participant does not refuse the collection, continue with the urine collection process.
 - If the participant refuses the collection, indicate that this is fine, thank the participant for his/her time, and record the refusal and the reason::

- If the participant has a physical limitation that prevents him/her from providing a urine specimen, record “Physical limitation.”
- If participant becomes ill during the visit or has an emergency that requires termination of the visit, record “Participant ill/emergency.”
- If there was a language issue due to the participant’s primary language not being English record, “Language issue.”
- If there was not a sufficient amount of time for the urine collection, record “No time.”
- If the participant was unable to urinate, record “Unable to urinate.”
- If the participant was uncomfortable with the collection procedures, record “Uncomfortable with collection procedures.”
- If the participant refused for a reason other than those listed, record “Other” and specify.
- If the participant was unwilling to provide a reason, record “Refused”.
- If the participant does not know why he/she did not continue with the collection, record “Don’t know”.

3. Read the urine collection questions to the participant and record the responses.

- *“When did you last urinate?”*
 - Record date and time. If the participant refuses to answer the question, record “Refused.” If the participant does not remember, record “Don’t know.”
- *“When was the last time you had anything to eat or drink?”*
 - Record date and time. If the participant refuses to answer the question, record “Refused.” If the participant does not remember, record “Don’t know.”
- *“How much of what you ate was beef, pork, tuna, or salmon?”*
 - Read each of the choices (none, less than one-quarter of the meal, one-quarter to one-half of the meal, more than one-half but less than three-quarters of the meal, three-quarters or more, but not all of the meal, all of the meal) and record how much was eaten.
 - If the participant refuses to answer the question, record “Refused”.
 - If the participant does not remember or does not know, record “Don’t know”.
- *“Do you take creatine supplements?”*

- If the participant asks, explain that creatine supplements are often taken by athletes wishing to gain muscle mass.
 - Record “Yes,” “No,” “Refused,” or “Don’t Know.”
4. Locate the adult urine collection supplies.
 5. Verify that the Specimen ID label is affixed to the side of the urine collection container and is readable and not damaged.
 6. Give the pre-labeled, unopened urine collection container, a Kim Wipe, and the Adult Urine Collection Instructions to the participant. The participant may refer to the collection instructions when collecting the urine specimen.
 7. While the participant is in the bathroom collecting the urine specimen, put on a lab coat, cleanse hands, and put on gloves.
 8. Place the biospecimen collection tray on a flat surface laying a Chux Pad on top of the tray.
 9. When the participant returns, thank the participant for providing the urine sample (or for trying if no sample was collected) and ask him/her to place the specimen on the biospecimen collection tray.
 10. Check the lid of the urine collection container to make sure it is securely closed.
 11. Record the status of the urine collection as either “Collected” or “Not collected.” Any amount of urine in the collection cup is considered a collected sample. If the urine was not collected, record the reason:
 - If the participant has a physical limitation that prevents him/her from providing a urine specimen, record “Physical limitation”.
 - If participant becomes ill during the visit or has an emergency that requires termination of the visit, record “Participant ill/Emergency”.
 - If there were issues with the collection equipment, record “Collection supplies malfunctioned”.
 - If there was a language issue due to the participant’s primary language being Spanish record, “Language issue, Spanish”.
 - If there was a language issue due to the participant’s primary language being other than Spanish record, “Language issue, non-Spanish”.
 - If the participant has a cognitive disability that prevents him/her from understanding the instructions, record “Cognitive disability”.

- If there was not a sufficient amount of time for the urine collection, record “No time”.
- If the urine specimen was not collected for a reason other than those listed, record “Other” and specify.
- If the urine specimen was not collected because the participant refused, record “Refused”.
- If the reason the urine specimen was not collected was unknown, record “Don’t know”.

12. Record the Specimen ID number on the urine collection container.

13. Place the urine specimen in the biohazard transport bag with the absorbent pad and seal the bag.

14. Put on the dry ice glove to place the sealed bag with the collection container upright on dry ice in the transport cooler.

- Be sure to refer to local ROC Hazard Communication Plan for proper handling of dry ice.

15. Record the date and time the urine specimen was collected.

16. Record where the urine collection occurred: in the participant’s home, at a clinic, at a hospital, or other location and specify.

17. Record any comments, problems, or concerns pertaining to the urine specimen collection.

2.3 Clean-Up Procedures

1. After completing the urine collection procedures, make sure the work area is clean.

- If a spill has occurred, follow the local ROC Exposure Control Plan to clean up the spill.

2. After performing clean-up procedures, discard gloves and cleanse hands with hand sanitizer.

3. Be sure any trash is packed properly in either the general trash bag or the biohazard waste bag for transport. All supplies used can be discarded in the general trash unless they are visibly contaminated with blood in which case they should be placed into a biohazard waste bag for disposal as medical waste. All trash, both general and biohazard, must be disposed of properly at the SHL.

3.0 Receipt and Storage Procedures for Adult Urine

Following transport of urine specimens to the SHL, they are to be receipted, placed in a pressure bag, and stored at -30°C until they are shipped weekly to the NCS Repository.

Multiple types of frozen biospecimens may be stored together in the same pressure bag, as long as they are not overcrowded. Urine, saliva, and breast milk specimens should be stored upright; blood tubes should be stored on their side until they are frozen to reduce the possibility of tube breakage due to the expansion of tube contents during freezing. For specific details on the number of biospecimens that can be stored in each pressure bag, refer to the Biospecimen Overview of Activities.

3.1 Receipt and Storage Equipment and Supplies

- PPE per local ROC Exposure Control Plan (e.g., gloves, lab coat, etc.)
- Freezer, -30°C
- Temperature monitoring and alarm system for freezer
- Pressure bag, approx. 7" x 12"
- Computer with barcode scanner that includes automated system for electronic data capture
- Biospecimen Tracking System - developed by the ROC IMS Hub to capture information for the Operational Data Element (ODE) tables
 - Hard-copy PAPI or other backup mechanism for recording ODEs in the event that the automated Biospecimen Tracking System is inaccessible

3.2 Procedures for Adult Urine Receipt and Storage

These procedures assume that the urine receipt and storage process and the recording of information about the process are conducted in such a way that the biospecimen integrity is maintained and there is little or no delay in recording information in the Biospecimen Tracking System as soon as an activity is completed.

Note: Data such as location of receipt and storage, staff receipting the specimen, as well as the date and time the specimen is receipted and stored at the SHL may be automatically captured in the Biospecimen Tracking System and may not need to be entered by the ROC data collector.

Always use standard precautions when handling biospecimens. Refer to local ROC Exposure Control Plan.

1. Put on a lab coat and gloves.
2. Open the transport cooler and put on the dry ice glove to remove the urine collection container (in its biohazard transport bag) from the dry ice chamber.
 - Note: To prevent premature thawing and refreezing, limit the time the urine specimen is not on dry ice and is exposed to room temperature when checking and recording information.
3. Confirm that the urine specimen is frozen, the collection container has no personal identifying information, and the Specimen ID label is readable and not damaged.
4. Record the Specimen ID from the urine specimen container and the condition of the urine specimen upon receipt (e.g., damaged, thawed, or other additional comments).
5. Place the urine specimen collection container (in its biohazard transport bag) into a pressure bag. Do not seal the pressure bag.
6. Place the pressure bag in a -30°C freezer.
7. Record the storage information for every specimen in the pressure bag including the storage location where the specimen is stored and the time placed in storage.
8. If during storage the freezer temperature rises above -25°C, refer to the Biospecimen Overview of Activities for information on documenting temperature events in the Biospecimen Tracking System.
9. If any problems other than temperature events occur during the storage of the urine specimen prior to shipment, record a comment to describe the problem and resolution (if any).
10. When the pressure bag is removed from the freezer to be placed in a shipping container, record the date and time it is removed from storage.

Refer to the Biospecimen Shipping Procedures for information on the shipment of biospecimens.