

Urine Collection and Transport Procedures

2.1 Adult Urine

Adult urine specimens will be collected at the P1 mother, T1 mother, T1 father, and T3 mother study events. Adult urine specimens will be analyzed to obtain information about physiological conditions and environmental exposures.

A participant may provide a urine specimen at any time during a specified visit. However, for visits during which both urine and vaginal specimens are collected, it is preferred that the participant self-collects the vaginal specimens at the same time (i.e., during the same bathroom visit) as the urine specimen.

2.1.1 Equipment, Supplies, and Forms

The following equipment and supplies are required to collect and transport adult urine:

- Adult Urine Collection Kit (kit contents are in the next list)
- Specimen collection tray
- Disposable laboratory coat
- Gloves
- Hand sanitizer
- Biohazard waste bag
- Biospecimen transport cooler
- Dry ice
- Dry ice glove
- Computer tablet with bar code scanner
- Computer keyboard cover.

The Adult Urine Collection Kit contains the following items:

- One urine collection container with lid
- One biohazard transport bag
- Two absorbent pads
- Two paper towels
- Adult Urine Collection Instructions
- One adhesive label for the collection container (UR01 label)
- One adhesive label for Biospecimen Transmittal Form (TM label)
- One adhesive label for hard copy backup Adult Urine Data Collection Form (DC label)
- Three additional adhesive labels for collection container (EX labels).

The following form is required to collect and transport adult urine specimens:

- Event-specific Biospecimen Transmittal Form (see volume Appendices VIII-B through VIII-G for forms and field-by-field instructions).

Urine collection data will be documented in the Biospecimen instrument in the Field-Administered Collection Environment (FACE). If FACE is not available, then the appropriate hard copy backup Adult Urine Data Collection Form must be used to document collection data (see Appendices 2-A and 2-B for form and field-by-field instructions). Once the system becomes available, data must be entered in the system from the backup form.

2.1.2 Step-by-Step Procedures for Adult Urine Collection

Always use universal precautions when handling biospecimens. Refer to Part 9 of Volume I for documentation of safety incidents.

The following procedures are to be used for adult urine collection. For general guidance on how to use FACE for data collection activities, refer to the FACE User Guide. For detailed question-by-question specifications for administering the Biospecimen instrument, refer to the appropriate section in volume Appendix VIII-A.

1. Put on a disposable laboratory coat.
2. Place the computer keyboard cover on the keyboard if you have not already done so. This will prevent the keyboard from contamination when handling specimens during the visit. One keyboard cover will be used for the duration of the biospecimen collection.
3. Launch the Biospecimen Data Collection instrument (Module 1) of FACE on the tablet. If FACE is not available, the hard copy backup Adult Urine Data Collection Form should be used.

P1 Mother, T1 Mother, T3 Mother

Follow the prompt in FACE to give the participant the option of collecting the vaginal swabs at the same time she is collecting the urine specimen (i.e., during the same bathroom visit).

4. Read the urine collection questions to the participant from FACE and enter the responses. If FACE is not available, read the collection questions in Part B of the hard copy backup Adult Urine Data Collection Form and record the responses.

P1 Mother, T1 Mother, T3 Mother

If both urine and vaginal swabs are to be collected during the same bathroom visit, FACE will prompt the user to ask the vaginal swab collection questions at this time. If FACE is not available read the collection questions in Part B of the hard copy backup Vaginal Swab Data Collection Form and record the responses.

5. Locate the Adult Urine Collection Kit and event-specific Biospecimen Transmittal Form.

P1 Mother, T1 Mother, T3 Mother

If both urine and vaginal swabs are to be collected during the same bathroom visit, also locate the Vaginal Swab Collection Kit. Follow the procedures in Chapter 3 of this part and volume to provide the participant with the Vaginal Swab Collection Kit and instructions simultaneously with the urine kit and instructions.

6. Wand the collection kit bar code into FACE and validate the kit type and expiration date.

7. If the kit type is valid and the kit is not expired, open the kit and remove the urine collection container, instructions, and labels. Remove the urine collection container from the plastic bag. If the urine collection container is not pre-labeled, place the UR01 label on the urine collection container.
8. Give the labeled urine collection container to the participant for collection.
9. Instruct the participant in the urine self-collection procedures using the Adult Urine Collection Instructions (see Appendix 2-C). The participant may refer to the collection instructions when collecting the specimen.
10. While the participant is in the bathroom collecting the specimens, do the following:
 - a. Place the TM label on the Biospecimen Transmittal Form.
 - b. If FACE is not available during the collection procedures, the hard copy backup Adult Urine Data Collection Form should be used. Place an extra subject label (from the visit coordinator's supplies) in the appropriate place on the form and place the DC label in the appropriate place on the form.
 - c. Put on gloves.
11. Place the specimen collection tray on a flat surface.
12. When the participant returns with the specimen:
 - a. Thank the participant for providing the specimen and ask him or her to place it on the specimen collection tray, and
 - b. Check the lid of the urine collection container to make sure it is securely closed.

2.1.3 Documenting Adult Urine Collection

1. Record the urine collection status in FACE and wand the bar code label on the urine collection container.
2. Place the urine specimen in the biohazard transport bag with the absorbent pad and seal the bag. Wearing the dry ice glove, immediately place the sealed bag on dry ice in the transport cooler.
3. Record any comments pertaining to the urine specimen collection in FACE (up to a 250-character limit) or on the hard copy backup Adult Urine Data Collection Form. If using the backup form, ensure the form is complete.
4. Record the urine collection status on the Biospecimen Transmittal Form.

5. If an incident occurs during the urine collection procedures, an Incident Report Form must be completed and the incident must be reported to the appropriate personnel. Refer to Part 9 of Volume I for more information regarding documentation of incidents.

2.1.4 Clean-Up Procedures

- After completing the urine collection procedures, make sure the work area is clean and reusable.
 - The work area is reusable if contamination, such as a spill, has *not* occurred.
 - If a spill has occurred, clean the tray with a bleach wipe. Discard items in the biohazard waste bag.
 - If the urine specimen is the last biospecimen collected at the visit, remove the computer keyboard cover, clean the work area and pack all collection supplies.
- After performing clean-up procedures, remove your gloves, discard them in the biohazard waste bag, and cleanse your hands with hand sanitizer. Be sure to pack the biohazard waste bag appropriately for transport so that it is not visible upon leaving the site of data collection. The biohazard waste bag must be disposed of properly at the Specimen Processing and Shipping Center (SPSC).

2.1.5 Transport Procedures

Urine specimens will be transported to the SPSC in the dry ice chamber of the biospecimen transport cooler.

- Ensure the Biospecimen Transmittal Form is complete. If this is the last biospecimen type collected at the visit, place the completed form in the zippered document pouch inside the lid of the transport cooler along with any unused labels.
- Secure the biohazard transport bag containing the urine container in the dry ice and confirm the cooler is properly closed for transport.

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Part 2

Appendix 2-A

Adult Urine Data Collection Form

Appendix 2-A.
Adult Urine Data Collection Form

	<p>National Children's Study Adult Urine Data Collection Form</p> <p style="font-size: small;">T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad</p>
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(Only for use when FACE is not available)

Part A: Administrative	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / 2 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="font-size: x-small; margin-left: 20px;">m m d d y y y y</p> <p>Data Collector ID:</p> <p style="text-align: center;"><input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p> <hr/> <p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <div style="border: 1px solid black; width: fit-content; margin: 10px auto; padding: 5px; text-align: center;"> Place Adult Urine Collection DC Label Here </div> <p>Time specimens received <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p>	<p>Collection Status (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial Complete <input type="checkbox"/> Not done</p> <p>Reason for Not Done/Partial (Mark one)</p> <p><input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other - specify _____</p>
Part B: Adult Urine Collection Questions	
<p>1. When did you last urinate? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <i>¿A qué hora orinó por última vez?</i></p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	
<p>2. When was the last time you had anything to eat or drink other than water? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m. <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i></p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	

Subject Label

Assignment ID,
Subject ID, Event Type

ADUCPT01.00DU



**Appendix 2-A.
Adult Urine Data Collection Form (continued)**

<p>3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon? <i>La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?</i></p> <table style="width:100%;"> <tr> <td><input type="checkbox"/> None / <i>Nada</i></td> <td><input type="checkbox"/> Three quarters to all of the meal / <i>De tres cuartos a toda la comida</i></td> </tr> <tr> <td><input type="checkbox"/> Less than one quarter of the meal / <i>Menos de un cuarto de la comida</i></td> <td><input type="checkbox"/> All of the meal / <i>Toda la comida</i></td> </tr> <tr> <td><input type="checkbox"/> One quarter to one half of the meal / <i>De un cuarto a la mitad de la comida</i></td> <td><input type="checkbox"/> Refused</td> </tr> <tr> <td><input type="checkbox"/> Less than three quarters of the meal / <i>Menos de tres cuartos de la comida</i></td> <td><input type="checkbox"/> Don't know</td> </tr> </table>		<input type="checkbox"/> None / <i>Nada</i>	<input type="checkbox"/> Three quarters to all of the meal / <i>De tres cuartos a toda la comida</i>	<input type="checkbox"/> Less than one quarter of the meal / <i>Menos de un cuarto de la comida</i>	<input type="checkbox"/> All of the meal / <i>Toda la comida</i>	<input type="checkbox"/> One quarter to one half of the meal / <i>De un cuarto a la mitad de la comida</i>	<input type="checkbox"/> Refused	<input type="checkbox"/> Less than three quarters of the meal / <i>Menos de tres cuartos de la comida</i>	<input type="checkbox"/> Don't know
<input type="checkbox"/> None / <i>Nada</i>	<input type="checkbox"/> Three quarters to all of the meal / <i>De tres cuartos a toda la comida</i>								
<input type="checkbox"/> Less than one quarter of the meal / <i>Menos de un cuarto de la comida</i>	<input type="checkbox"/> All of the meal / <i>Toda la comida</i>								
<input type="checkbox"/> One quarter to one half of the meal / <i>De un cuarto a la mitad de la comida</i>	<input type="checkbox"/> Refused								
<input type="checkbox"/> Less than three quarters of the meal / <i>Menos de tres cuartos de la comida</i>	<input type="checkbox"/> Don't know								
<p>4. Do you take creatine supplements? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>¿Toma suplementos de creatina?</i> <input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>									
Part C: Adult Urine Collection									
<p>UR01 Urine collection container</p>	<p>Collection Status (Mark one.)</p> <input type="checkbox"/> Collected (END) <input type="checkbox"/> Not Collected								
<p>Reason for Not Collected (Mark one.)</p> <input type="checkbox"/> Quantity not sufficient (<40ml) <input type="checkbox"/> Other - specify _____ <input type="checkbox"/> Refused									
<p>Comments:</p> <hr/> <hr/> <hr/>									

<p>Data Collector ID for field QC</p> <div style="text-align: center;"> <input style="width: 20px; height: 20px;" type="text"/> </div>

<p>Date entered into CHITA: <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> / <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> / 2 0 <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/> <input style="width: 20px; height: 20px;" type="text"/></p> <p style="text-align: center; font-size: small;">m m d d y y y y</p>
<p>ID of Data Collector who entered the form:</p> <div style="text-align: center;"> <input style="width: 20px; height: 20px;" type="text"/> </div>



Part 2

Appendix 2-B

Adult Urine Data Collection Form:
Field-by-Field Instructions

**Appendix 2-B.
Adult Urine Data Collection Form: Field-by-Field Instructions**

**ADULT URINE DATA COLLECTION FORM:
FIELD-BY-FIELD INSTRUCTIONS**

This form is only to be used when the Field-Administration Collection Environment (FACE) is not available and should be completed by the biospecimen data collector at the P1 mother, T1 mother, T1 father and T3 mother data collection visits. Instructions for completing each item on the form are provided in this field-by-field.

After Completing the Form

- Within 2 hours of the visit, the form should be checked to make sure that it is accurate, legible, and complete.
- Make sure that all of the appropriate boxes are completely filled. Comments should be limited to the area provided.
- The biospecimen data collector who checks the form for completion should write her data collector ID in the space provided at the bottom of the last page.
- The data collector who enters the data in FACE should record the date of data entry and her data collector ID in the spaces provided on the last page of the form.



National Children's Study
Adult Urine
Data Collection Form

T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/></p> <p style="text-align: center; font-size: small;">m m d d y y y y</p> <p>Data Collector ID:</p> <p style="text-align: center;"><input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p> <hr/> <p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <div style="border: 1px solid black; width: fit-content; margin: 10px auto; padding: 5px; text-align: center;"> Place Adult Urine Collection DC Label Here </div> <p>Time specimens received <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p>	<p>Collection Status (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial Complete <input type="checkbox"/> Not done</p> <p>Reason for Not Done/Partial (Mark one)</p> <p><input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other - specify _____</p>
Part B: Adult Urine Collection Questions	
<p>1. When did you last urinate? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <i>¿A qué hora orinó por última vez?</i> <input type="checkbox"/> p.m.</p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	
<p>2. When was the last time you had anything to eat or drink other than water? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i> <input type="checkbox"/> p.m.</p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	

Subject Label

Assignment ID,
 Subject ID, Event Type

ADUCPT01.00DU





Part A: Administrative Section

- *Date*—Record the date that the adult urine collection was completed or attempted. The month, day, and the last two digits of the year should be recorded (e.g., 02/07/2002). The date of collection should not be recorded in advance of the participant’s study visit.
- *Data Collector ID*—Record the data collector ID of the person who completes the form.
- *Visit location*—Mark the box corresponding to the location of the visit.
- *Collection status (Select one)*—Mark the box that corresponds to the status of the adult urine collection.
 - “Complete”—Mark this box to indicate that the specimen was collected.
 - “Partial complete”—Mark this box to indicate that the urine collection was attempted but the participant did not collect any urine.
 - “Not done”—Mark this box to indicate that the participant did not provide a urine specimen. When this box is marked indicate the reason that the urine specimen was not collected.
- *Reason for Not Done/Partial (Mark one)*—Mark the box that corresponds to the choice that best explains why the urine specimen was not done or was partially completed. If the reason is determined prior to giving the Adult Urine Collection Kit to the participant, complete this section and the items in Part A as described; however, do not open the Adult Urine Collection Kit or complete Parts B and C.
 - “Participant refusal”—Mark this box to indicate that the participant was unwilling to provide a urine specimen.
 - “Participant Ill/emergency”—Mark this box to indicate that the participant became ill during the visit and was unable to provide a urine specimen. This box also is marked if the participant has an emergency that requires termination of the visit prior to the collection of the urine specimen. Record a brief description of the nature of the emergency or illness in the Comments section of Part C.
 - “No time”—Mark this box to indicate that the urine specimen was not collected because the visit is ended ahead of schedule. Record a brief description of the reason that the visit was ended in the Comments section in Part C.



National Children's Study
Adult Urine
Data Collection Form

T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/></p> <p style="text-align: center; font-size: small;">m m d d y y y y</p> <p>Data Collector ID:</p> <p style="text-align: center;"><input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p> <hr/> <p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <div style="border: 1px solid black; width: fit-content; margin: 10px auto; padding: 5px; text-align: center;"> Place Adult Urine Collection DC Label Here </div> <p>Time specimens received <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p>	<p>Collection Status (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial Complete <input type="checkbox"/> Not done</p> <p>Reason for Not Done/Partial (Mark one)</p> <p><input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other - specify _____</p>
Part B: Adult Urine Collection Questions	
<p>1. When did you last urinate? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <i>¿A qué hora orinó por última vez?</i> <input type="checkbox"/> p.m.</p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	
<p>2. When was the last time you had anything to eat or drink other than water? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i> <input type="checkbox"/> p.m.</p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	

Subject Label

Assignment ID,
 Subject ID, Event Type

ADUCPT01.00DU





- “Safety exclusion”—This code does not apply to this biospecimen collection activity.
- “Physical limitations”—Mark this box to indicate that the participant has a physical limitation that prevented him or her from providing a urine specimen. Record a brief description of the type of physical limitation in the Comments section in Part C.
- “Quantity not sufficient”—This code does not apply to this biospecimen collection activity.
- “Defective collection kit”—Mark this box to indicate that the urine specimen was not collected because of a problem with the Adult Urine Collection Kit. This includes not having the appropriate supplies available in the home or clinic.
- “Slide broken”—This code does not apply to this biospecimen collection activity.
- “Language issue, Spanish”—Mark this box to indicate that the urine specimen was not collected because the biospecimen data collector does not speak Spanish well enough to communicate the necessary instructions to the participant.
- “Language issue, non-Spanish”—Mark this box to indicate that the urine specimen was not collected because the biospecimen data collector is unable to communicate the necessary instructions to the participant.
- “Cognitive disability”—Mark this box to indicate that the urine specimen was not collected because the participant is cognitively or developmentally impaired and therefore unable to understand the specimen collection instructions.
- “Parent/guardian refusal”—Mark this box to indicate that the participant is younger than 18 years old and his or her parent or guardian refused to allow her to provide a urine specimen.
- “Other—specify”—Mark this box to indicate that the urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.
- *Time collection kit opened*—Record the time the Adult Urine Collection Kit was opened. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example if data collection kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”



National Children's Study
Adult Urine
Data Collection Form

T1-1st, T1-Prior, P1, T3-1st, T3 Prior, T1 Dad

(Only for use when FACE is not available)

Part A: Administrative	
<p>Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> 2 <input type="text"/> 0 <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;">m m d d y y y y</p> <p>Data Collector ID:</p> <p style="text-align: center;"><input type="text"/> <input type="text"/></p> <p>Visit location: <input type="checkbox"/> Home <input type="checkbox"/> Clinic/Office</p>	<p>Collection Status (Mark one.) <input type="checkbox"/> Complete <input type="checkbox"/> Partial Complete <input type="checkbox"/> Not done</p> <p>Reason for Not Done/Partial (Mark one)</p> <p><input type="checkbox"/> Participant refusal <input type="checkbox"/> Participant III/emergency <input type="checkbox"/> No time <input type="checkbox"/> Safety exclusion <input type="checkbox"/> Physical limitations <input type="checkbox"/> Quantity not sufficient <input type="checkbox"/> Defective collection kit <input type="checkbox"/> Slide broken <input type="checkbox"/> Language issue, Spanish <input type="checkbox"/> Language issue, non-Spanish <input type="checkbox"/> Cognitive disability <input type="checkbox"/> Parent/guardian refusal <input type="checkbox"/> Other - specify _____</p>
<p>Time collection kit opened <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p> <div style="border: 1px solid black; padding: 5px; text-align: center; width: fit-content; margin: 10px auto;"> <p>Place Adult Urine Collection DC Label Here</p> </div> <p>Time specimens received <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <input type="checkbox"/> p.m.</p>	
Part B: Adult Urine Collection Questions	
<p>1. When did you last urinate? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <i>¿A qué hora orinó por última vez?</i> <input type="checkbox"/> p.m.</p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	
<p>2. When was the last time you had anything to eat or drink other than water? <input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/> <input type="checkbox"/> a.m. <i>¿A que hora comió o bebió algo por última vez, aparte de agua?</i> <input type="checkbox"/> p.m.</p> <p style="text-align: right;"><input type="checkbox"/> Refused <input type="checkbox"/> Don't know</p>	

Subject Label

Assignment ID,
 Subject ID, Event Type

ADUCPT01.00DU



- *Time specimen received*—Record the time that the urine specimen is given to the data collector. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example if the urine specimen is received at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”
- *Kit Label*—Before reviewing the Adult Urine Collection Instructions with the participant, open the Adult Urine Collection Kit and place the “DC” label in the appropriate place on the form.

Part B: Adult Urine Collection Questions

1. *When did you last urinate?*

Record the time of the participant’s last urination prior to collecting the specimen. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the participant last urinated at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.” If the participant refuses to answer or does not know, mark the corresponding box.

2. *When was the last time you had anything to eat or drink other than water?*

Record the time that the participant reports last eating or drinking anything other than water. Be sure to zero fill the spaces when necessary and to mark the box to indicate “a.m.” or “p.m.” For example, if the kit is opened at 2:05 p.m., record “02:05” and mark the box corresponding to “p.m.”

Subject Label

Obtain a subject label from the visit coordinator’s biospecimen folder and affix it to the bottom right corner of the data collection form.



3. The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon?
La última vez que comió, ¿qué tanto de lo que comió era carne de res, cerdo, bacalao, atún o salmón?

None / *Nada*
 Three quarters to all of the meal / *De tres cuartos a toda la comida*
 Less than one quarter of the meal / *Menos de un cuarto de la comida*
 All of the meal / *Toda la comida*
 One quarter to one half of the meal / *De un cuarto a la mitad de la comida*
 Refused
 Less than three quarters of the meal / *Menos de tres cuartos de la comida*
 Don't know

4. Do you take creatine supplements? Yes No
¿Toma suplementos de creatina? Refused Don't know

Part C: Adult Urine Collection

<p>UR01 Urine collection container</p>	<p>Collection Status (Mark one.)</p> <input type="checkbox"/> Collected (END) <input type="checkbox"/> Not Collected
<p>Reason for Not Collected (Mark one.)</p> <input type="checkbox"/> Quantity not sufficient (<40ml) <input type="checkbox"/> Other - specify _____ <input type="checkbox"/> Refused	

Comments:

Data Collector ID for field QC

Date entered into CHITA: / / 2 0

m m d d y y y y

ID of Data Collector who entered the form:



3. *The last time that you ate, how much of what you ate was beef, pork, cod, tuna, or salmon?*

Read each of the responses and mark the box that corresponds to the participant's response. If the participant refuses to answer or does not know, mark the corresponding box.

4. *Do you take creatine supplements?*

Mark the box that corresponds to the participant's response. If the participant refuses to answer or does not know, mark the corresponding box.

Part C: Adult Urine Collection

- *Collection Status* (Mark one)—Mark the box that corresponds to the status of the adult urine collection.
 - “Collected”—Mark this box to indicate that the specimen was collected. When the specimen is collected, no additional information is required and the form is complete.
 - “Not collected”—Mark this box to indicate that the participant did not provide a urine specimen. When this box is marked, indicate the reason that the urine specimen was not collected.
- *Reason for Not Collected* (Mark one)—Mark the box that corresponds to the choice that best explains why the specimen was not collected.
 - “Quantity not sufficient” (<40mL)
 - “Other—specify”—Mark this box to indicate that the adult urine specimen was not collected for a reason other than those listed; specify the reason in the space provided.
 - “Refused”—Mark this box to indicate that the participant is unwilling to provide a urine specimen.
- *Comments*—Additional comments may include reasons that the urine specimen was not collected or problems encountered during the collection that may affect analysis. Problems with post-collection processing also should be recorded here.

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Part 2

Appendix 2-C

Adult Urine Collection Instructions

**Appendix 2-C.
Adult Urine Collection Instructions**

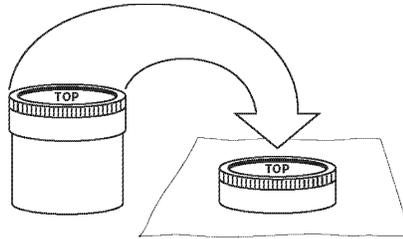
OMB Control Number: 0925-0593
Expiration Date: 09/30/2011

**National Children's Study
Adult Urine Collection Instructions**

As part of the National Children's Study, we ask you to collect a sample of your urine.
This kit includes everything you will need to collect the sample: a prelabeled urine collection cup with lid and 2 paper towels.

Instructions

1. Wash your hands with soap and water.
2. Lay one paper towel on a flat surface. Unscrew the lid from the collection cup and place it on the paper towel. The inside of the lid should be placed face down on the paper towel. Do not touch the inside of the lid or the collection cup. Do not allow the inside of the collection cup or the inside of the lid to come in contact with any part of your body, clothing, or bathroom surfaces.



3. Start urinating into the toilet, then urinate directly into the collection cup. If possible, fill the cup at least half full. Do not fill to overflowing.
4. Screw the lid on the collection cup immediately so that the urine is only briefly exposed to the air.
5. Use the other paper towel to wipe any urine from the outside of the cup.
6. Remember to wash your hands with soap and water after collecting the sample.
7. Give the collection cup back to the study staff.

If you have any questions please ask study staff.

Thank you for providing this sample!

Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). Do not return the completed form to this address.

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**Appendix 2-C.
Adult Urine Collection Instructions (continued)**

Número de control de OMB: 0925-0593
Fecha de vencimiento: 09/30/2011

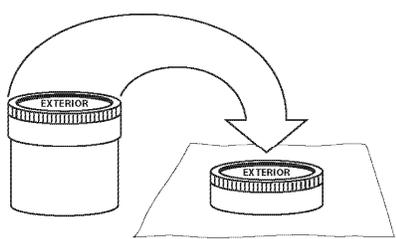
**Estudio Nacional de los Niños
Instrucciones para tomar la muestra de orina de un adulto**

Como parte del Estudio Nacional de los Niños queremos pedirle que tome una muestra de su orina.

Con estos materiales usted tendrá todo lo que necesita para tomar la muestra, incluyendo un envase con tapa para muestras de orina previamente etiquetado y 2 toallas de papel.

Instrucciones

1. Lávese las manos con agua y jabón.
2. Extienda una toalla de papel en una superficie plana. Quite la tapa del envase y póngala sobre la toalla. El interior de la tapa debe quedar boca abajo sobre la toalla. No toque el interior de la tapa ni el interior del envase. Tampoco permita que el interior del envase ni el de la tapa toquen ninguna parte de su cuerpo, ropa o las superficies del baño.



3. Comience a orinar en el inodoro o excusado y continúe orinando directamente dentro del envase para la muestra. Si es posible, llene el envase al menos hasta la mitad. No permita que se derrame.
 4. Ajuste la tapa del envase de inmediato para que la orina no esté en contacto con el aire más que por unos breves momentos.
 5. Con la otra toalla de papel, limpie el exterior del envase.
 6. Recuerde lavarse bien las manos con agua y jabón después de tomar la muestra.
 7. Entregue el envase al personal del estudio.
-

Si tiene alguna pregunta, por favor pregunte al personal del estudio.

¡Gracias por darnos esta muestra!

Se calcula que el promedio de tiempo necesario para esta recolección de información es de 7 minutos por entrevista, incluyendo el tiempo para leer las instrucciones, buscar fuentes de información existentes, reunir y mantener la información necesaria y completar y revisar la recolección de información. **Ninguna agencia puede llevar a cabo ni patrocinar una recolección de información y ninguna persona está obligada a responder a dicha recolección a menos que ésta muestre un número de control vigente de OMB.** Envíe los comentarios acerca de este cálculo de tiempo necesario, incluyendo sugerencias sobre cómo reducirlo, o acerca de cualquier otro aspecto de esta recolección de información a: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0593). No devuelva el formulario contestado a esta dirección.

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