



Adult Urine Instrument

Event Category:	Trigger-Based, Pre-Preg, PV1, PV2; Time-Based, Birth, 6M, 12M, 36M, 60M
Event:	Pre-Preg, PV1, PV2, Birth, 6M, 12M, 36M, 60M
Instrument Target:	Pre-Pregnant Woman; Pregnant Women; Biological Mother; Primary Caregiver
Instrument Respondent:	Pre-Pregnant Woman; Pregnant Women; Biological Mother; Primary Caregiver
Domain:	Biospecimen
Document Category:	Sample Collection
Method:	Data Collector Administered
Mode (for this instrument*):	In-Person, CAI
OMB Approved Modes:	In-Person, CAI
Estimated Administration Time:	11 minutes
Multiple Child/Sibling Consideration:	Per Event
Special Considerations:	N/A
Version:	2.0
MDES Release:	4.0

*This instrument is OMB-approved for multi-mode administration but this version of the instrument is designed for administration in this/these mode(s) only.

Public reporting burden for this collection of information is estimated to average 11 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.

This page intentionally left blank.

Adult Urine Instrument

TABLE OF CONTENTS

GENERAL PROGRAMMER INSTRUCTIONS:..... 1
BIOSPECIMEN URINE COLLECTION..... 3

This page intentionally left blank.

Adult Urine Instrument

GENERAL PROGRAMMER INSTRUCTIONS:

WHEN PROGRAMMING INSTRUMENTS, VALIDATE FIELD LENGTHS AND TYPES AGAINST THE MDES TO ENSURE DATA COLLECTION RESPONSES DO NOT EXCEED THOSE OF THE MDES. SOME GENERAL ITEM LIMITS USED ARE AS FOLLOWS:

DATA ELEMENT FIELDS	MAXIMUM CHARACTERS PERMITTED	DATA TYPE	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	CHARACTER	
UNIT AND PHONE FIELDS	10	CHARACTER	
_OTH AND COMMENT FIELDS	255	CHARACTER	<ul style="list-style-type: none"> • Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	<ul style="list-style-type: none"> • Limit text to 30 characters
ALL ID FIELDS	36	CHARACTER	
ZIP CODE	5	NUMERIC	
ZIP CODE LAST FOUR	4	NUMERIC	
CITY	50	CHARACTER	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	NUMERIC CHARACTER	<ul style="list-style-type: none"> • DISPLAY AS MM/DD/YYYY • STORE AS YYYY-MM-DD • HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	<ul style="list-style-type: none"> • HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59

Instrument Guidelines for Participant and Respondent IDs:

PRENATALLY, THE **P_ID** IN THE MDES HEADER IS THAT OF THE PARTICIPANT (E.G. THE NON-PREGNANT WOMAN, PREGNANT WOMAN, OR THE FATHER).

POSTNATALLY, A RESPONDENT ID WILL BE USED IN ADDITION TO THE PARTICIPANT ID BECAUSE SOMEBODY OTHER THAN THE PARTICIPANT MAY BE COMPLETING THE INTERVIEW. FOR EXAMPLE, THE PARTICIPANT MAY BE THE CHILD AND THE RESPONDENT MAY BE THE MOTHER, FATHER, OR ANOTHER CAREGIVER.

THEREFORE, MDES VERSION 2.2 AND ALL FUTURE VERSIONS CONTAIN A **R_P_ID** (RESPONDENT PARTICIPANT ID) HEADER FIELD FOR EACH POST-BIRTH INSTRUMENT. THIS WILL ALLOW ROCs TO INDICATE WHETHER THE RESPONDENT IS SOMEBODY OTHER THAN THE PARTICIPANT ABOUT WHOM THE QUESTIONS ARE BEING ASKED.

A REMINDER:

ALL RESPONDENTS MUST BE CONSENTED AND HAVE RECORDS IN THE PERSON, PARTICIPANT, PARTICIPANT_CONSENT AND LINK_PERSON_PARTICIPANT TABLES, WHICH CAN BE PRELOADED INTO EACH INSTRUMENT. ADDITIONALLY, IN POST-BIRTH QUESTIONNAIRES WHERE THERE IS THE ABILITY TO LOOP THROUGH A SET OF QUESTIONS FOR MULTIPLE CHILDREN, IT IS IMPORTANT TO CAPTURE AND STORE THE CORRECT CHILD **P_ID** ALONG WITH THE LOOP INFORMATION. IN THE MDES VARIABLE LABEL/DEFINITION COLUMN, THIS IS INDICATED AS FOLLOWS: **EXTERNAL IDENTIFIER: PARTICIPANT ID FOR CHILD DETAIL.**

BIOSPECIMEN URINE COLLECTION

(TIME_STAMP_BUC_ST).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP.
- PRELOAD PARTICIPANT ID (**P_ID**) AND RESPONDENT ID (**R_P_ID**) FOR ADULT.

BUC01000/(URINE_INTRO). You will now collect a urine sample. I will need to ask you some questions before you collect your urine sample.

Label	Code	Go To
CONTINUE	1	BUC05000
REFUSED	-1	

SOURCE

National Children's Study, Legacy Phase

BUC02000/(REFUSAL_REASON). I am sorry that you have chosen not to participate in this collection. Can you tell me why?

DATA COLLECTOR INSTRUCTIONS

- ENTER REASON FOR REFUSAL.

Label	Code	Go To
PHYSICAL LIMITATION	1	BUC04000
PARTICIPANT ILL/EMERGENCY	2	BUC04000
LANGUAGE ISSUE	3	BUC04000
NO TIME	4	BUC04000
UNABLE TO URINATE	5	BUC04000
UNCOMFORTABLE WITH COLLECTION PROCEDURES	6	BUC04000
OTHER	-5	
REFUSED	-1	BUC04000
DON'T KNOW	-2	BUC04000

SOURCE

National Children's Study, Legacy Phase (Modified) (6M Child)

BUC03000/(REFUSAL_REASON_OTH).

SPECIFY: _____

SOURCE

National Children's Study, Legacy Phase (Modified) (6M Child)

BUC04000. That's fine. Thank you for your time.

SOURCE
New

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none">• GO TO COLLECTION_COMMENT

BUC05000. When did you last urinate?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none">• RECORD DATE AS "MMDDYYYY."• RECORD THE TIME AS HH:MM. BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND CHOOSE "AM" OR "PM". FOR EXAMPLE, IF TIME OF LAST URINATION WAS AT 2:05 PM RECORD "02:05" AND CHOOSE "PM".

SOURCE
National Children's Study, Legacy Phase

(LT_URINE_MM) LAST URINATION – DATE: MONTH

|_|_|
M M

Label	Code	Go To
REFUSED	-1	
DON'T KNOW	-2	

(LT_URINE_DD) LAST URINATION – DATE: DAY

|_|_|
M M

Label	Code	Go To
REFUSED	-1	
DON'T KNOW	-2	

(LT_URINE_YYYY) LAST URINATION – DATE: YEAR

|_|_|_|
Y Y Y Y

(LT_URINE_TIME) LAST URINATION – TIME

|_|_| : |_|_|
H H M M

Label	Code	Go To
REFUSED	-1	
DON'T KNOW	-2	

(LT_URINE_TIME_UNIT) LAST URINATION – AM/PM

Label	Code	Go To
AM	1	
PM	2	
REFUSED	-1	
DON'T KNOW	-2	

BUC06000. When was the last time you had anything to eat or drink?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> RECORD THE LAST TIME PARTICIPANT ATE OR DRANK. RECORD DATE AS "MMDDYYYY." RECORD THE TIME AS HH:MM. BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND CHOOSE "AM" OR "PM". FOR EXAMPLE, IF THE LAST TIME PARTICIPANT ATE OR DRANK WAS AT 2:05 PM RECORD "02:05" AND CHOOSE "PM".

SOURCE
National Children's Study, Legacy Phase (modified)

(LT_EAT_DRINK_MM) LAST TIME ATE OR DRANK – DATE: MONTH

M		M	

Label	Code	Go To
REFUSED	-1	
DON'T KNOW	-2	

(LT_EAT_DRINK_DD) LAST TIME ATE OR DRANK – DATE: DAY

D		D	

Label	Code	Go To
REFUSED	-1	
DON'T KNOW	-2	

(LT_EAT_DRINK_YYYY) LAST TIME ATE OR DRANK – DATE: YEAR

Y		Y		Y	

(LT_EAT_DRINK_TIME) LAST TIME ATE OR DRANK – TIME

		:				
H			M		M	

(LT_EAT_DRINK_TIME_UNIT) LAST TIME ATE OR DRANK – AM/PM

Label	Code	Go To
AM	1	
PM	2	
REFUSED	-1	
DON'T KNOW	-2	

BUC07000/(ATE_MEAT). How much of what you ate was beef, pork, tuna, or salmon?

Label	Code	Go To
NONE	1	
Less than one quarter of the meal	2	
One quarter to one half of the meal	3	
More than one-half but less than three quarters of the meal	4	
Three quarters or more, but not all of the meal	5	
All of the meal	6	
REFUSED	-1	
DON'T KNOW	-2	

SOURCE

National Children's Study, Legacy Phase

BUC08000/(CREATINE_SUPP). Do you take creatine supplements?

DATA COLLECTOR INSTRUCTIONS

- IF THE PARTICIPANT ASKS, EXPLAIN THAT CREATINE SUPPLEMENTS ARE OFTEN TAKEN BY ATHLETES WISHING TO GAIN MUSCLE MASS.

Label	Code	Go To
YES	1	
NO	2	
REFUSED	-1	
DON'T KNOW	-2	

SOURCE

National Children's Study, Legacy Phase

BUC09000/(SPECIMEN_STATUS). URINE COLLECTION STATUS

DATA COLLECTOR INSTRUCTIONS

- READ URINE COLLECTION INSTRUCTIONS TO THE PARTICIPANT.
- PREPARE THE WORK AREA WHILE THE PARTICIPANT IS COLLECTING SPECIMEN.

DATA COLLECTOR INSTRUCTIONS

- PUT ON LAB COAT AND GLOVES.
- THANK THE PARTICIPANT FOR THEIR SAMPLE (OR FOR TRYING IF NO SAMPLE WAS COLLECTED).
- ENTER THE STATUS OF THE URINE COLLECTION

Label	Code	Go To
COLLECTED	1	
NOT COLLECTED	2	

PROGRAMMER INSTRUCTIONS

- IF SPECIMEN_STATUS = 2, GO TO SPECIMEN_COMMENTS.
- IF SPECIMEN_STATUS = 1, AND
 - IF EVENT_TYPE = 18 (BIRTH EVENT), GO TO NCS_CUP.
 - OTHERWISE, IF EVENT_TYPE ≠ 18 (BIRTH EVENT), GO TO SPECIMEN_ID.

BUC1000/(SPECIMEN_COMMENTS). URINE COLLECTION TECHNICAL COMMENTS

DATA COLLECTOR INSTRUCTIONS

- ENTER THE REASON THE SAMPLE WAS NOT COLLECTED.
- SELECT ONLY ONE RESPONSE.

Label	Code	Go To
PHYSICAL LIMITATION	1	COLLECTION_COMMENT
PARTICIPANT ILL/ EMERGENCY	2	COLLECTION_COMMENT
COLLECTION SUPPLIES MALFUNCTIONED	3	COLLECTION_COMMENT
QUANTITY NOT SUFFICIENT	4	COLLECTION_COMMENT
LANGUAGE ISSUE, SPANISH	5	COLLECTION_COMMENT
LANGUAGE ISSUE, NON SPANISH	6	COLLECTION_COMMENT
COGNITIVE DISABILITY	7	COLLECTION_COMMENT
NO TIME	8	COLLECTION_COMMENT
OTHER	-5	
REFUSED	-1	COLLECTION_COMMENT
DON'T KNOW	-2	COLLECTION_COMMENT

BUC11000/(SPECIMEN_COMMENT_OTH). URINE COLLECTION TECHNICAL COMMENT OTHER SPECIFY

DATA COLLECTOR INSTRUCTIONS

- IF THERE ARE ANY OTHER URINE COLLECTION TECHNICAL COMMENTS NOT

DATA COLLECTOR INSTRUCTIONS

LISTED IN THE PREVIOUS QUESTION, ENTER THE REASON BELOW.

PROGRAMMER INSTRUCTIONS

- GO TO **COLLECTION_COMMENT**.

BUC12000/(NCS_CUP). WAS AN NCS-PROVIDED URINE CUP USED FOR THE SPECIMEN COLLECTION?

Label	Code	Go To
YES	1	
NO	2	
REFUSED	-1	
DON'T KNOW	-2	

BUC13000/(SPECIMEN_ID). SPECIMEN ID

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

DATA COLLECTOR INSTRUCTIONS

- RECORD URINE COLLECTION CUP SPECIMEN ID WHEN PARTICIPANT RETURNS WITH THE SAMPLE.
- IMMEDIATELY PLACE COLLECTION CUP IN DRY ICE CHAMBER OF THE TRANSPORT COOLER PER TRANSPORT INSTRUCTIONS.

PROGRAMMER INSTRUCTIONS

- CANNOT BE NULL
- HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT TWO ALPHA, SEVEN NUMERIC CHARACTERS DASH TWO ALPHA, TWO NUMERIC CHARACTERS (AA ### ## ##-AA##)

BUC14000.

DATA COLLECTOR INSTRUCTIONS

- RECORD DATE AND TIME THE ADULT URINE SPECIMEN WAS COLLECTED.
- RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.
- RECORD THE TIME AS HH:MM, BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO MARK THE BOX TO CHOOSE "AM" OR "PM". FOR EXAMPLE, IF THE ADULT URINE SAMPLE WAS COLLECTED AT 2:05PM, RECORD "02:05" AND CHOOSE "PM".

(A_URINE_COLL_MM) DATE ADULT URINE SPECIMEN WAS COLLECTED - MONTH

M	M		

(A_URINE_COLL_DD) DATE ADULT URINE SPECIMEN WAS COLLECTED - DAY

--	--	--	--

D D

(A_URINE_COLL_YYYY) DATE ADULT URINE SPECIMEN WAS COLLECTED - YEAR

|_|_|_|_|
Y Y Y Y

(A_URINE_COLL_TIME) TIME ADULT URINE SPECIMEN COLLECTED

|_|_|_|:|_|_|_|
H H M M

(A_URINE_COLL_TIME_UNIT) TIME ADULT URINE SPECIMEN COLLECTED - AM/PM

Label	Code	Go To
AM	1	
PM	2	

BUC15000/(COLLECTION_LOCATION). COLLECTION LOCATION

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> RECORD WHERE URINE COLLECTION OCCURRED.

Label	Code	Go To
HOME	1	BUC16000
CLINIC	2	BUC16000
HOSPITAL	3	BUC16000
OTHER LOCATION	-5	

BUC15100/(COLLECTION_LOCATION_OTH).

SPECIFY:

BUC16000. Thank you for your time and participation in this sample collection.

SOURCE
National Children's Study, Vanguard Phase

BUC17000/(COLLECTION_COMMENT). RECORD ANY COMMENTS ABOUT THE ADULT URINE COLLECTION.

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE ADULT URINE COLLECTION PROCEDURE.

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_BUC_ET
COMMENTS	2	

BUC18000/(COLLECTION_COMMENT_OTH). SPECIFY:

(TIME_STAMP_BUC_ET).

PROGRAMMER INSTRUCTIONS

- | |
|--|
| <ul style="list-style-type: none">• INSERT DATE/TIME STAMP |
|--|