



Child Urine Instrument

Event Category:	Time-Based
Event:	6M, 12M, 36M, 60M
Administration:	N/A
Instrument Target:	Child
Instrument Respondent:	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:	14 minutes
Multiple Child/Sibling Consideration:	Per Child
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 14 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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Child Urine Instrument

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Child 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**) FOR CHILD AND RESPONDENT ID (**R_P_ID**) FOR ADULT CAREGIVER.
- PRELOAD CHILD'S FIRST NAME AND DISPLAY NAME IN **C_FNAME** THROUGHOUT INSTRUMENT
- OTHERWISE, IF **C_FNAME** = -1 OR -2, DISPLAY "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT.

BUC00100/(URINE_INTRO). I would like to collect a sample of {C_FNAME/the child}'s urine. Before I do so, I will explain this collection and ask you some questions.

DATA COLLECTOR INSTRUCTIONS

- IF THE CHILD IS NOT TOILET-TRAINED THE URINE SPECIMEN WILL BE COLLECTED WITH THE URINE BAG. EXPLAIN THE COLLECTION PROCEDURE USING THE CHILD URINE BAG COLLECTION INSTRUCTIONS AND BE SURE TO INFORM THE ADULT CAREGIVER THAT:
 - o SHE/HE NEEDS TO BE PRESENT WHILE THE BAG IS APPLIED AND REMOVED FROM THE CHILD.
 - o THE ADHESIVE ON THE BAG MAY CAUSE A MILD IRRITATION.
- IF THE CHILD IS TOILET-TRAINED, THE URINE WILL BE COLLECTED WITH A URINE COLLECTION CUP. EXPLAIN THE COLLECTION PROCEDURE USING THE CHILD URINE COLLECTION INSTRUCTIONS.
- IF THE ADULT CAREGIVER REFUSES THE COLLECTION, SELECT REFUSED. OTHERWISE, SELECT CONTINUE.

Label	Code	Go To
CONTINUE	1	COLLECTION_METHOD
REFUSED	-1	

SOURCE

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

BUC03000/(REFUSE_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
CONCERN ABOUT ALLERGIC REACTION/SKIN	1	BUC05000

Label	Code	Go To
IRRITATION		
CHILD HAS A DIAPER RASH	2	BUC05000
PHYSICAL LIMITATION	3	BUC05000
PARTICIPANT ILL/EMERGENCY	4	BUC05000
LANGUAGE ISSUE	5	BUC05000
NO TIME	6	BUC05000
UNABLE TO URINATE	7	BUC05000
UNCOMFORTABLE WITH COLLECTION PROCEDURES	8	BUC05000
OTHER	-5	
REFUSED	-1	BUC05000
DON'T KNOW	-2	BUC05000

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

BUC04000/(REFUSE_REASON_OTH).
SPECIFY: _____

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

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

BUC05000. That's fine. Thank you for your time.

SOURCE
National Children's Study, Vanguard Phase (Adult Blood)

PROGRAMMER INSTRUCTIONS
• GO TO COLLECTION_COMMENT.

BUC06000/(COLLECTION_METHOD). HOW WILL THE URINE BE COLLECTED?

DATA COLLECTOR INSTRUCTIONS
• MARK THE CHOICE THAT INDICATES HOW THE CHILD'S URINE WILL BE COLLECTED.

Label	Code	Go To
NCS PROVIDED URINE BAG	1	BUC09000
NCS PROVIDED CUP	2	BUC08000

Label	Code	Go To
OTHER	-5	

BUC07000/(COLLECTION_METHOD_OTH). SPECIFY: _____

BUC08000. When did {C_FNAME/the child} 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 (6M Child)

(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

|_|_|
D D

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

(LT_URINE_YYYY) LAST URINATION – DATE: YEAR

|_|_|_|
Y Y Y Y

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

(LT_URINE_2) LAST URINATION – TIME

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

Label	Code	Go To
REFUSED	-1	

Label	Code	Go To
DON'T KNOW	-2	

(LT_URINE_3) LAST URINATION – AM/PM

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

PROGRAMMER INSTRUCTIONS
• GO TO BUC10000.

BUC09000. When was the last time {C_FNAME/the child}'s diaper was changed?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> RECORD WHEN DIAPER WAS LAST CHANGED. ENTER A TWO-DIGIT MONTH, A TWO-DIGIT DAY, AND A 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 LAST TIME CHILD WAS CHANGED WAS AT 2:05 PM, RECORD "02:05" AND CHOOSE "PM."

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

(LAST_CHANGE_MM) LAST DIAPER CHANGE - DATE: MONTH

|_|_|
M M

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

(LAST_CHANGE_DD) LAST DIAPER CHANGE – DATE: DAY

|_|_|
D D

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

(LAST_CHANGE_YYYY) LAST DIAPER CHANGE – DATE: YEAR

|_|_|_|
Y Y Y Y

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

(LAST_CHANGE_TIME) LAST DIAPER CHANGE - TIME

			:			
H	H			M	M	

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

(LAST_CHANGE_TIME_UNIT) LAST DIAPER CHANGE – AM/PM

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

BUC10000. When was the last time {C_FNAME/the child} had anything to eat or drink?

DATA COLLECTOR INSTRUCTIONS

- RECORD THE LAST TIME CHILD ATE OR DRANK ANYTHING.
- ENTER A TWO-DIGIT MONTH, A TWO-DIGIT DAY, AND A 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 LAST TIME CHILD DRANK WAS AT 2:05 PM, RECORD “02:05” AND CHOOSE “PM.”

SOURCE

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

(LT_EAT_DRINK_MM) LAST EAT OR DRINK - DATE: MONTH

M	M	

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

(LT_EAT_DRINK_DD) LAST EAT OR DRINK - DATE: DAY

D	D	

Label	Code	Go To
REFUSED	-1	

Label	Code	Go To
DON'T KNOW	-2	

(LT_EAT_DRINK_YYYY) LAST EAT OR DRINK - DATE: YEAR

Y	Y	Y	Y

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

(LT_EAT_DRINK_TIME) LAST EAT OR DRINK - TIME

		:		
H	H		M	M

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

(LT_EAT_DRINK_TIME_UNIT) LAST EAT OR DRINK – AM/PM

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

BUC11000/(ATE_MEAT). How much of what {C_FNAME/the child} 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 (Modified)

PROGRAMMER INSTRUCTIONS

- IF **COLLECTION_METHOD** = 1, GO TO **CARE_PRODUCTS**.
- IF **COLLECTION_METHOD** = 2 OR -5, GO TO **SPECIMEN_STATUS**.

BUC12000/(CARE_PRODUCTS). Have you or anyone else used any of the following products on the child's diaper area in the past 24 hours?

DATA COLLECTOR INSTRUCTIONS

- READ THE CHOICES BELOW TO THE ADULT CAREGIVER AND RECORD THE RESPONSE FOR EACH.
- SELECT ALL THAT APPLY.
- PROBE: Any others?
- IF THERE ARE ANY OTHER PRODUCTS USED THAT ARE NOT LISTED, SELECT OTHER AND SPECIFY THE PRODUCT TYPE.

Label	Code	Go To
Child powder/talc/cornstarch	1	
Diaper cream/ointment	2	
Vaseline	3	
Child wipes	4	
Child shampoo/body wash	5	
Child lotion	6	
Baby oil	7	
NONE	8	
OTHER	-5	
REFUSED	-1	
DON'T KNOW	-2	

SOURCE

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

PROGRAMMER INSTRUCTIONS

- IF **CARE_PRODUCTS** = ANY COMBINATION OF 1 THROUGH 7, GO TO **CLEANSE_METHOD**.
- IF **CARE_PRODUCTS** = -5 OR ANY COMBINATION OF 1 THROUGH 7 AND -5, GO TO **CARE_PRODUCTS_OTH**.
- IF **CARE_PRODUCTS** = 8, -1 OR -2, DO NOT ALLOW SELECTION OF ADDITIONAL RESPONSES AND GO TO **TIME_STAMP_BUC_ET**.

BUC12100/(CARE_PRODUCTS_OTH).

SPECIFY: _____

SOURCE

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

(**TIME_STAMP_BUC_ET**).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP

DATA COLLECTOR COMPLETED QUESTIONS

(TIME_STAMP_DCC_ST).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP

DCC01000/(CLEANSE_METHOD). HOW WAS THE CHILD'S GENITAL AREA CLEANSED?

DATA COLLECTOR INSTRUCTIONS

- MARK THE CHOICE THAT INDICATES HOW THE CHILD'S GENITAL AREA WAS CLEANSED PRIOR TO APPLICATION OF THE COLLECTION BAG.

Label	Code	Go To
SOAP AND WATER	1	
WATER ONLY	2	
DID NOT CLEANSE	3	PLACED_BAG_1

DCC02000/(CLEANSE_DONE_BY). WHO CLEANSED THE CHILD'S GENITAL AREA?

DATA COLLECTOR INSTRUCTIONS

- RECORD WHO CLEANSED THE CHILD. IF OTHER THAN DATA COLLECTOR OR ADULT CAREGIVER, SPECIFY.

Label	Code	Go To
DATA COLLECTOR	1	PLACED_BAG_1
ADULT CAREGIVER	2	PLACED_BAG_1
OTHER	-5	

DCC03000/(CLEANSE_DONE_BY_OTH).

SPECIFY: _____

DCC04000/(PLACED_BAG_1). WHO PLACED THE URINE BAG ON THE CHILD?

DATA COLLECTOR INSTRUCTIONS

- RECORD WHO PLACED THE URINE BAG ON THE CHILD.

Label	Code	Go To
DATA COLLECTOR	1	BAG_2_USED
ADULT CAREGIVER	2	BAG_2_USED
ADULT CAREGIVER REFUSED BAG PLACEMENT	3	COLLECTION_COMMENT
OTHER	-5	

DCC05000/(PLACED_BAG_1_OTH). SPECIFY: _____

DCC06000/(BAG_2_USED). WAS A SECOND BAG USED?

DATA COLLECTOR INSTRUCTIONS	
<ul style="list-style-type: none"> RECORD YES IF A SECOND BAG WAS USED. RECORD NO IF A SECOND BAG WAS NOT USED. RECORD REFUSED IF A SECOND BAG WAS REFUSED. 	

Label	Code	Go To
YES	1	
NO	2	SPECIMEN_STATUS
ADULT CAREGIVER REFUSED BAG PLACEMENT	3	COLLECTION_COMMENT

DCC07000/(BAG_2_USED_REASON). REASON FOR USING SECOND BAG.

Label	Code	Go To
FIRST BAG LEAKED	1	PLACED_BAG_2
FIRST BAG TORN/PULLED OFF	2	PLACED_BAG_2
FIRST BAG SPILLED	3	PLACED_BAG_2
BOWEL MOVEMENT	4	PLACED_BAG_2
OTHER	-5	

DCC08000/(BAG_2_USED_REASON_OTH).

SPECIFY:

DCC09000/(PLACED_BAG_2). WHO PLACED THE SECOND BAG ON THE CHILD?

DATA COLLECTOR INSTRUCTIONS	
<ul style="list-style-type: none"> RECORD WHO PLACED THE SECOND URINE BAG ON THE CHILD. 	

Label	Code	Go To
DATA COLLECTOR	1	SPECIMEN_STATUS
ADULT CAREGIVER	2	SPECIMEN_STATUS
OTHER	-5	

DCC10000/(PLACED_BAG_2_OTH). SPECIFY: _____

DCC11000/(SPECIMEN_STATUS). STATUS OF THE URINE COLLECTION

DATA COLLECTOR INSTRUCTIONS	
<ul style="list-style-type: none"> ENTER THE STATUS OF THE URINE COLLECTION. 	

Label	Code	Go To
COLLECTED	1	
NOT COLLECTED	2	

PROGRAMMER INSTRUCTIONS	
<ul style="list-style-type: none"> IF SPECIMEN_STATUS = 1 AND COLLECTION_METHOD = 1, GO TO BAG_REMOVED_BY. IF SPECIMEN_STATUS = 1 AND COLLECTION_METHOD = 2 OR -5, GO TO 	

PROGRAMMER INSTRUCTIONS
SPECIMEN_ID. <ul style="list-style-type: none"> IF SPECIMEN_STATUS = 2, GO TO NO_SPECIMEN_REASON.

DCC12000/(NO_SPECIMEN_REASON).

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> ENTER THE REASON WHY SPECIMEN WAS NOT COLLECTED. SELECT ONLY ONE RESPONSE.

Label	Code	Go To
BAG LEAKED	1	COLLECTION_LOCATION
BAG TORN/PULLED OFF	2	COLLECTION_LOCATION
BAG SPILLED	3	COLLECTION_LOCATION
CONTAINER/CUP SPILLED	4	COLLECTION_LOCATION
CUP LEAKED	5	COLLECTION_LOCATION
SPECIMEN CONTAMINATED	6	COLLECTION_LOCATION
PHYSICAL LIMITATION	7	COLLECTION_LOCATION
CAREGIVER ILL/EMERGENCY	8	COLLECTION_LOCATION
COLLECTION SUPPLIES MALFUNCTIONED	9	COLLECTION_LOCATION
NO URINE TO TRANSFER	10	COLLECTION_LOCATION
CHILD ILL/EMERGENCY	11	COLLECTION_LOCATION
NO TIME	12	COLLECTION_LOCATION
OTHER	-5	
REFUSED	-1	COLLECTION_LOCATION

DCC13000/(NO_SPECIMEN_REASON_OTH).

SPECIFY:

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> GO TO COLLECTION_LOCATION.

DCC14000/(BAG_REMOVED_BY). WHO REMOVED THE BAG FROM THE CHILD?

DATA COLLECTOR INSTRUCTIONS
<ul style="list-style-type: none"> RECORD WHO REMOVED THE URINE BAG FROM THE CHILD. IF OTHER THAN DATA COLLECTOR OR ADULT CAREGIVER, SPECIFY.

Label	Code	Go To
DATA COLLECTOR	1	SPECIMEN_ID
ADULT CAREGIVER	2	SPECIMEN_ID
OTHER	-5	

DCC15000/(BAG_REMOVED_BY_OTH). SPECIFY: _____

DCC16000/(SPECIMEN_ID). URINE COLLECTION CUP SPECIMEN ID

Label	Code	Go To
HOME	1	COLLECTION_COMMENT
CLINIC	2	COLLECTION_COMMENT
OTHER LOCATION	-5	

DCC19000/(COLLECTION_LOCATION_OTH).

SPECIFY:

DCC20000/(COLLECTION_COMMENT). RECORD ANY PROBLEMS OR CONCERNS ABOUT THE COLLECTION.

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

Label	Code	Go To
NO COMMENTS	1	DCC22000
COMMENT	2	

DCC21000/(COLLECTION_COMMENT_OTH).

SPECIFY:

DCC22000. {That's fine. Thank you for your time./Thank you for the child's participation in this sample collection.}

PROGRAMMER INSTRUCTIONS
<ul style="list-style-type: none"> IF PLACED_BAG_1 = 3, BAG_2_USED = 3, OR SPECIMEN_STATUS = 2, DISPLAY "That's fine. Thank you for your time." OTHERWISE DISPLAY, "Thank you for the child's participation in this sample collection."

(TIME_STAMP_DCC_ET).

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