



Biospecimen Child Urine Collection Instrument

Event:	6-Month, 12-Month
Participant:	Child
Respondent:	Parent/Caregiver
Domain:	Biospecimen
Type of Document:	Data Collection Instrument
Allowable Mode:	In-Person
Allowable Method:	CAPI
Recruitment Groups:	EH, PB, HI
Version:	1.0
Release:	MDES 3.0

Public reporting burden for this collection of information is estimated to average 10 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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Biospecimen Child Urine Collection Instrument

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BIOSPECIMEN URINE COLLECTION

(TIME_STAMP_1) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP.

PROGRAMMER INSTRUCTIONS:

- PRELOAD PARTICIPANT ID (**P_ID**) FOR CHILD AND RESPONDENT ID (**R_P_ID**) FOR RESPONDENT.
- PRELOAD CHILD'S FIRST NAME (**BABY_FNAME**) AND DISPLAY NAME FOR "CHILD'S NAME" THROUGHOUT DOCUMENT.
 - USE "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT IF CHILD'S NAME IS REFUSED.

CUP0100/(URINE_INTRO). I would like to collect a sample of {CHILD'S NAME/the child}'s urine. Before I do so, I will explain this collection and ask you some questions.

DATA COLLECTOR INSTRUCTIONS:

- EXPLAIN THE CHILD URINE COLLECTION PROTOCOL TO THE PARENT OR CAREGIVER.
- BE SURE TO INFORM THE PARENT OR CAREGIVER THAT:
 - SHE/HE NEEDS TO BE PRESENT WHILE THE BAG IS APPLIED AND REMOVED FROM THE CHILD.
 - THE ADHESIVE ON THE BAG MAY CAUSE A MILD IRRITATION.
- RECORD AGREEMENT OR REFUSAL TO COLLECT URINE SPECIMEN.

CONTINUE..... 1
REFUSED..... -1

CUP0100A/(RESP_REL). WHAT IS THE RELATIONSHIP OF THE PARENT OR CAREGIVER TO THE CHILD?

MOTHER..... 1
FATHER..... 2
OTHER..... -5

PROGRAMMER INSTRUCTIONS:

- IF **URINE_INTRO** = 1 AND **RESP_REL** = 1 OR 2, GO TO **COLLECTION_METHOD**.
- IF **URINE_INTRO** = -1 AND **RESP_REL** = 1 OR 2, GO TO **REFUSE_REASON**.
- OTHERWISE, IF **RESP_REL** = -5, GO TO **RESP_REL_OTH**.

CUP0100B/(RESP_REL_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTIONS:

- LIMIT TEXT TO 255 CHARACTERS.
- IF URINE_INTRO = 1, GO TO COLLECTION_METHOD.
- OTHERWISE, GO TO REFUSE_REASON.

CUP0100C/(REFUSE_REASON). I am sorry that you have chosen not to participate in this collection. Can you tell me why?

DATA COLLECTOR INSTRUCTION:

- ENTER REASON FOR REFUSAL. SPECIFY IF OTHER THAN ALLERGIC REACTION/IRRITATION OR DIAPER RASH.

CONCERN ABOUT ALLERGIC REACTION/SKIN IRRITATION..... 1 (CUP0150)
 CHILD HAS A DIAPER RASH..... 2 (CUP0150)
 OTHER.....-5
 REFUSED-1
 DON'T KNOW.....-2

CUP0100D/(REFUSE_REASON_OTH)

SPECIFY _____ (CUP0150)

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP0150. That's fine. Thank you for your time. (TIME_STAMP_2)

CUP0160/(COLLECTION_METHOD). HOW WILL THE URINE BE COLLECTED?

DATA COLLECTOR INSTRUCTION:

- MARK THE CHOICE THAT INDICATES HOW THE CHILD'S URINE WILL BE COLLECTED.

NCS PROVIDED URINE BAG.....1 (CUP0200)
 OTHER.....-5

CUP0170/(COLLECTION_METHOD_OTH)

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP0200/(LAST_CHANGE_DATE/LAST_CHANGE_TIME/LAST_CHANGE_TIME_UNIT).
When was the last time {CHILD'S NAME/the child}'s diaper was changed?

DATA COLLECTOR INSTRUCTIONS:

- 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."
- IF RESPONSE WAS DETERMINED TO BE INVALID, ASK QUESTION AGAIN AND PROBE FOR VALID RESPONSE.

CUP0200A/(LAST_CHANGE_DATE). LAST DIAPER CHANGE - DATE

|_|_|_| / |_|_|_| / |_|_|_|_|_|
M M D D Y Y Y Y

REFUSED -1
DON'T KNOW..... -2

CUP0200B/(LAST_CHANGE_TIME). LAST DIAPER CHANGE - TIME

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

REFUSED -1
DON'T KNOW..... -2

CUP0200C/(LAST_CHANGE_TIME_UNIT). LAST DIAPER CHANGE – AM/PM

AM..... 1
PM..... 2

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH OR DAY ARE NOT TWO DIGITS. (FILL THE SPACE WITH 0 AS NECESSARY.)
- HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
- HARD EDIT: INCLUDE HARD EDIT IF MONTH IS NOT BETWEEN 01 AND 12.

- HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
- FORMAT DATE AS YYYYMMDD.

CUP0300/(LAST_DRINK_DATE/LAST_DRINK_TIME/LAST_DRINK_TIME_UNIT). When was the last time {CHILD’S NAME/the child} had anything to drink?

DATA COLLECTOR INSTRUCTIONS:

- RECORD THE LAST TIME CHILD 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.”
- IF RESPONSE WAS DETERMINED TO BE INVALID, ASK QUESTION AGAIN AND PROBE FOR VALID RESPONSE.

CUP0300A/(LAST_DRINK_DATE). LAST DRINK - DATE

|_|_|_| / |_|_|_| / |_|_|_|_|
 M M D D Y Y Y Y

REFUSED -1
 DON'T KNOW..... -2

CUP0300B/(LAST_DRINK_TIME). LAST DRINK - TIME

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

REFUSED -1
 DON'T KNOW..... -2

CUP0300C/(LAST_DRINK_TIME_UNIT). LAST DRINK – AM/PM

AM..... 1
PM..... 2

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH OR DAY ARE NOT TWO DIGITS. (FILL THE SPACE WITH 0 AS NECESSARY.)
- HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
- FORMAT DATE AS YYYYMMDD.

CUP0350/(CARE_PRODUCTS). Have you or anyone else used any of the following products on your child's diaper area in the past 24 hours?

DATA COLLECTOR INSTRUCTIONS:

- READ THE CHOICES BELOW TO THE PARTICIPANT 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.

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
REFUSED.....-1
DON'T KNOW.....-2
OTHER.....-5

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 ANY OTHER RESPONSE, AND GO TO **CLEANSE_METHOD**.
- IF **CARE_PRODUCTS** = 8, -1 OR -2, DO NO ALLOW SELECTION OF ADDITIONAL RESPONSES.

CUP0400/(CARE_PRODUCTS_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

DATA COLLECTOR COMPLETED QUESTIONS

CUP0550/(CLEANSE_METHOD). HOW WAS THE CHILD'S GENITAL AREA CLEANSED?

DATA COLLECTOR INSTRUCTION:

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

SOAP AND WATER..... 1
WATER ONLY..... 2
DID NOT CLEANSE..... 3

CUP0600/(CLEANSE_DONE_BY). WHO CLEANSED THE CHILD'S GENITAL AREA?

DATA COLLECTOR INSTRUCTION:

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

DATA COLLECTOR.....1 **(PLACED_BAG_1)**
PARENT/CAREGIVER.....2 **(PLACED_BAG_1)**
OTHER.....-5

CUP0650/(CLEANSE_DONE_BY_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP0700/(PLACED_BAG_1). WHO PLACED THE URINE BAG ON THE CHILD?

DATA COLLECTOR INSTRUCTION:

- RECORD WHO PLACED THE URINE BAG ON THE CHILD.

DATA COLLECTOR.....1 **(BAG_2_USED)**
PARENT/CAREGIVER.....2 **(BAG_2_USED)**
OTHER-5
PARENT/CAREGIVER REFUSED
BAG PLACEMENT..... 3 **(CUP2000)**

CUP0750/(PLACED_BAG_1_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS

CUP0800/(BAG_2_USED) WAS A SECOND BAG USED?

DATA COLLECTOR INSTRUCTION:

- 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.

YES..... 1
NO 2 (**SPECIMEN_STATUS**)
PARENT/CAREGIVER REFUSED
BAG PLACEMENT.....3 (**TIME_STAMP_2**)

CUP0900/(BAG_2_USED_REASON) REASON FOR USING SECOND BAG.

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

CUP0900A/(BAG_2_USED_REASON_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS

CUP0901/(PLACED_BAG_2). WHO PLACED THE SECOND BAG ON THE CHILD?

DATA COLLECTOR INSTUCTION:

- RECORD WHO PLACED THE SECOND URINE BAG ON THE CHILD.

DATA COLLECTOR1 (**SPECIMEN_STATUS**)
PARENT/CAREGIVER.....2 (**SPECIMEN_STATUS**)
CUP2000OTHER-5

CUP0901A/(PLACED_BAG_2_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP1000/(SPECIMEN_STATUS). STATUS OF THE URINE COLLECTION

DATA COLLECTOR INSTRUCTION:

- ENTER THE STATUS OF THE URINE COLLECTION.

COLLECTED..... 1 (BAG_REMOVED_BY)
 NOT COLLECTED..... 2

CUP1600/(NO_SPECIMEN_REASON).

DATA COLLECTOR INSTRUCTIONS:

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

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)

CUP1600A/(NO_SPECIMEN_REASON_OTH).

SPECIFY _____ (COLLECTION_LOCATION)

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP1650/(BAG_REMOVED_BY). WHO REMOVED THE BAG FROM THE CHILD?

DATA COLLECTOR INSTRUCTION:

- RECORD WHO REMOVED THE URINE BAG FROM THE CHILD. IF OTHER THAN DATA COLLECTOR OR PARENT, SPECIFY.

DATA COLLECTOR.....1 (SPECIMEN_ID)
 PARENT/CAREGIVER.....2 (SPECIMEN_ID)
 OTHER.....-5

CUP1660/(BAG_REMOVED_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP1700/(SPECIMEN_ID). URINE COLLECTION CUP SPECIMEN ID

DATA COLLECTOR INSTRUCTIONS:

- RECORD URINE COLLECTION CUP SPECIMEN ID.
- FORMAT MUST BE AA #####-BU##

|_|_|_|_|_|_|_|_|_|_|_|_|_|-BU|_|_|_|_|

PROGRAMMER INSTRUCTIONS:

- CANNOT BE NULL.
- HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT AA #####-BU## (FORMAT MUST BE AA #####-BU##).

CUP1750/(URINE_COLLECT_DATE). DATE CHILD URINE SPECIMEN WAS COLLECTED

|_|_|_|_|/|_|_|_|_|/|_|_|_|_|_|_|_|_|_|
M M D D Y Y Y Y

CUP1750A/(URINE_COLLECT_TIME). TIME CHILD URINE SPECIMEN WAS COLLECTED

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

CUP1750B/(URINE_COLLECT_TIME_UNIT). TIME CHILD URINE SPECIMEN WAS COLLECTED – AM/PM

AM..... 1
PM..... 2

DATA COLLECTOR INSTRUCTION:

- RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH OR DAY ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)

- HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MONTH IS NOT BETWEEN 01 AND 12
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
- HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
- FORMAT DATE AS YYYYMMDD

CUP1800/(COLLECTION_LOCATION). WHERE DID THE URINE COLLECTION OCCUR?

DATA COLLECTOR INSTRUCTION:

- RECORD WHERE URINE COLLECTION OCCURRED OR WAS ATTEMPTED.

HOME.....1 (COLLECTION_COMMENT)
 CLINIC.....2 (COLLECTION_COMMENT)
 OTHER LOCATION.....-5

CUP1900/(COLLECTION_LOCATION_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP1900/(COLLECTION_COMMENT). RECORD ANY PROBLEMS OR CONCERNS ABOUT THE COLLECTION.

DATA COLLECTOR INSTRUCTION:

- DOCUMENT ANY PROBLEMS OR CONCERNS ABOUT THE CHILD URINE COLLECTION PROCEDURE.

NO COMMENTS.....1 (CUP2000)
 COMMENT.....2

CUP1900A/(COLLECTION_COMMENT_OTH).

SPECIFY _____

PROGRAMMER INSTRUCTION:

- LIMIT TEXT TO 255 CHARACTERS.

CUP2000. {That's fine. Thank you for your time./Thank you for your child's participation in this sample collection.}

PROGRAMMER INSTRUCTIONS:

- IF **PLACED_BAG_1** = 3 or **BAG_2_USED** = 3, DISPLAY "That's fine. Thank you for your time."
- OTHERWISE DISPLAY, "Thank you for your child's participation in this sample collection."

(TIME_STAMP_2) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP.