



Biospecimen Adult Urine Instrument

Event:	Pregnancy Visit 1, Pregnancy Visit 2, Birth
Participant:	Pregnant or Non-Pregnant Woman
Domain:	Biospecimen
Type of Document:	Data Collection Instrument
Recruitment Groups:	EH, PB, HI, PBS
Version:	1.1
Release:	MDES 3.3

Public reporting burden for this collection of information is estimated to average 15 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.

Biospecimen Adult Urine Instrument

TABLE OF CONTENTS

BIOSPECIMEN URINE COLLECTION.....	1
-----------------------------------	---

Biospecimen Adult Urine Instrument CAPI

BIOSPECIMEN URINE COLLECTION

(TIME_STAMP_1) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

UR0900/(URINE_INTRO). You will now collect a urine sample. I will need to ask you some questions before you collect your urine sample.

CONTINUE..... 1
REFUSED..... -1 (TIME_STAMP_2)

UR1000/(LT_URINE_1/LT_URINE_2/LT_URINE_3). When did you last urinate?

DATA COLLECTOR INSTRUCTIONS:

- RECORD DATE AS "MMDDYYYY."
- 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 TIME OF LAST URINATION WAS AT 2:05 PM RECORD "02:05" AND CHOOSE "PM".

UR1000A/(LT_URINE_1). LAST URINATION – DATE

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

UR1000B/(LT_URINE_2). LAST URINATION – TIME

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

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

UR1000C/(LT_URINE_3). LAST URINATION – AM/PM

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

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

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MINUTES ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
- HARD EDIT: INCLUDE HARD EDIT IF HOUR IS NOT BETWEEN 01 AND 12
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59
- FORMAT DATE AS YYYYMMDD
- 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 < 2011.

UR1100/(LT_EAT_DRINK_1/LT_EAT_DRINK_2/LT_EAT_DRINK_3). When was the last time you had anything to eat or drink other than water?

DATA COLLECTOR INSTRUCTIONS:

- RECORD THE LAST TIME PARTICIPANT ATE OR DRANK OTHER THAN WATER.
- THE TWO DIGIT MONTH, THE TWO DIGIT DAY, AND THE FOUR DIGIT YEAR SHOULD BE RECORDED. RECORD DATE AS "MMDDYYYY."
- 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 PARTICIPANT ATE OR DRANK WAS AT 2:05 PM RECORD "02:05" AND CHOOSE "PM".
- **UR1100A/(LT__EAT_DRINK_1).** LAST TIME ATE OR DRANK – DATE

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

UR1100B/(LT_EAT_DRINK_2)). LAST TIME ATE OR DRANK – TIME

_	_	:	_	_
H	H		M	M

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

UR1100C/(LT_EAT_DRINK_3). LAST TIME ATE OR DRANK – AM/PM

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

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOUR OR MINUTES ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
- HARD EDIT: INCLUDE HARD EDIT IF HOUR IS NOT BETWEEN 01 AND 12
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59
- FORMAT DATE AS YYYYMMDD
- 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 < 2011.

UR1200/(ATE_MEAT). How much of what you ate was beef, pork, tuna, or salmon?

NONE..... 1
 Less than one quarter of the meal..... 2
 One quarter to one half of the meal..... 3
 Less than three quarters of the meal..... 4
 Three quarters to all of the meal..... 5
 All of the meal..... 6
 REFUSED.....-1
 DON'T KNOW.....-2

UR1300/(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.

YES..... 1
 NO..... 2
 REFUSED..... -1
 DON'T KNOW..... -2

DATA COLLECTOR INSTRUCTIONS:

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

- PUT ON LAB COAT AND GLOVES.

UR1500/(SPECIMEN_STATUS). URINE COLLECTION STATUS

DATA COLLECTOR INSTRUCTIONS:

- THANK THE PARTICIPANT FOR THEIR SAMPLE (OR FOR TRYING IF NO SAMPLE WAS COLLECTED).
- ENTER THE STATUS OF THE URINE COLLECTION

COLLECTED..... 1 **(SPECIMEN_ID)**
 NOT COLLECTED..... 2

UR1600A/(SPECIMEN_COMMENTS). URINE COLLECTION TECHNICAL COMMENTS

DATA COLLECTOR INSTRUCTIONS:

- ENTER THE REASON THE SAMPLE WAS NOT COLLECTED. SELECT ONLY ONE RESPONSE.
- IF THE PARTICIPANT HAS A PHYSICAL LIMITATION THAT PREVENTS HIM/HER FROM PROVIDING A URINE SPECIMEN CHOOSE "PHYSICAL LIMITATION".
- IF PARTICIPANT BECOMES ILL DURING THE VISIT AND IS UNABLE TO PROVIDE A URINE SPECIMEN OR HAS AN EMERGENCY THAT REQUIRES TERMINATION OF THE VISIT BEFORE A URINE SPECIMEN IS COLLECTED CHOOSE "PARTICIPANT ILL/EMERGENCY".
- IF THE COLLECTION EQUIPMENT WAS NOT AVAILABLE AND URINE SAMPLE WAS NOT COLLECTED CHOOSE "COLLECTION EQUIPMENT NOT AVAILABLE."
- IF THE URINE SAMPLE QUANTITY WAS NOT SUFFICIENT FOR ANALYSIS CHOOSE "QUANTITY NOT SUFFICIENT."
- IF THERE WAS A LANGUAGE ISSUE DUE TO THE PARTICIPANT'S PRIMARY LANGUAGE BEING SPANISH CHOOSE "LANGUAGE ISSUE, SPANISH"
- IF THERE WAS A LANGUAGE ISSUE DUE TO THE PARTICIPANT'S PRIMARY LANGUAGE BEING A LANGUAGE OTHER THAN SPANISH CHOOSE "LANGUAGE ISSUE, NON SPANISH."
- IF THE PARTICIPANT HAS A COGNITIVE DISABILITY THAT PREVENTS HIM/HER FROM UNDERSTANDING THE INSTRUCTIONS AND PROVIDING A URINE SPECIMEN CHOOSE "COGNITIVE DISABILITY."
- IF THERE WAS NOT A SUFFICIENT AMOUNT OF TIME FOR THE URINE SPECIMEN COLLECTION CHOOSE "NO TIME."

PHYSICAL LIMITATION..... 1 **(TIME_STAMP_2)**

PARTICIPANT ILL/ EMERGENCY.....	2	(TIME_STAMP_2)
COLLECTION EQUIPMENT NOT AVAILABLE.....	3	(TIME_STAMP_2)
QUANTITY NOT SUFFICIENT.....	4	(TIME_STAMP_2)
LANGUAGE ISSUE, SPANISH.....	5	(TIME_STAMP_2)
LANGUAGE ISSUE, NON SPANISH.....	6	(TIME_STAMP_2)
COGNITIVE DISABILITY.....	7	(TIME_STAMP_2)
NO TIME.....	8	(TIME_STAMP_2)
OTHER.....	-5	
REFUSED.....	-1	(TIME_STAMP_2)
DON'T KNOW.....	-2	(TIME_STAMP_2)

UR1600B/(SPECIMEN_COMMENT_OTH). URINE COLLECTION TECHNICAL COMMENT
OTHER SPECIFY

DATA COLLECTOR INSTRUCTION:

- IF THERE ARE ANY OTHER URINE COLLECTION TECHNICAL COMMENTS NOT LISTED IN THE PREVIOUS QUESTION, ENTER THE REASON BELOW.

_____ (TIME_STAMP_2)

PROGRAMMER INSTRUCTION:

- LIMIT FREE TEXT TO 255 CHARACTERS

UR1700/(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.
- FORMAT MUST BE AA #####-UR##

|_|_|_|_|_|_|_|_|_|_|_|_|_|-UR|_|_|_|_|

PROGRAMMER INSTRUCTIONS:

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

UR1800/(COLLECTION_LOCATION). COLLECTION LOCATION

DATA COLLECTOR INSTRUCTIONS:

- RECORD WHERE URINE COLLECTION OCCURRED.

HOME..... 1

CLINIC..... 2
OTHER LOCATION..... 3

PROGRAMMER INSTRUCTIONS:

- IF STUDY CENTER IS PARTICIPATING IN LOI3-ENV-01-D AND **SPECIMEN_STATUS = 1**, GO TO **UR_COLL_DIFFICULT**.
- OTHERWISE, GO TO **TIME_STAMP_2**.

DATA COLLECTOR INSTRUCTIONS:

- ASK THE FOLLOWING QUESTIONS OF THE PARTICIPANT:

UR1900/(UR_COLL_DIFFICULT). Was the urine collection difficult for you?

YES..... 1
NO..... 2
REFUSED..... -1
DON'T KNOW..... -2

UR2000/(UR_COLL_EASIER_COMMENT). Is there anything that would make the urine sample collection easier for you?

COMMENT _____

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

PROGRAMMER INSTRUCTION:

- LIMIT FREE TEXT TO 255 CHARACTERS

(TIME_STAMP_2) DATE/TIME STAMP PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP