



## Biospecimen Placenta and Umbilical Cord Data Collection Instrument

<b>Event:</b>	Birth
<b>Participant:</b>	Mother
<b>Domain:</b>	Biospecimen
<b>Type of Document:</b>	Data Collection Instrument
<b>Allowable Mode:</b>	In-person (CAPI)
<b>Allowable Method:</b>	Interviewer-Administered
<b>Recruitment Groups:</b>	EH, PB, HI, PBS
<b>Version:</b>	1.0
<b>Release:</b>	MDES 3.3

Public reporting burden for this collection of information is estimated to average 5 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 Placenta and Umbilical Cord Data Collection 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	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	
UNIT AND PHONE FIELDS	10	
_OTH AND COMMENT FIELDS	255	
FIRST NAME AND LAST NAME	30	
ALL ID FIELDS	36	
ZIP CODE	5	
ZIP CODE LAST FOUR	4	
CITY	50	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	<ul style="list-style-type: none"> <li>• DISPLAY AS MM/DD/YYYY</li> <li>• STORE AS YYYY-MM-DD</li> <li>• HARD EDITS: MM MUST EQUAL 00 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.</li> </ul>
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	<ul style="list-style-type: none"> <li>• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59</li> </ul>

## **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 STUDY CENTERS 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.**

**DATA COLLECTOR-COMPLETED QUESTIONS**

**(TIME\_STAMP\_PUC\_ST) PROGRAMMER INSTRUCTION:**

- INSERT DATE/TIME STAMP.

**PUC001.** AS PART OF THE NATIONAL CHILDREN'S STUDY (NCS), WE ARE ASKING YOU TO COLLECT THE PLACENTA AND ATTACHED UMBILICAL CORD. ALL THE MATERIALS NEEDED FOR THIS COLLECTION ARE INCLUDED IN THE NCS PLACENTA AND UMBILICAL CORD COLLECTION KIT. PLEASE FOLLOW THE INSTRUCTIONS IN THE KIT AND COMPLETE ALL RELEVANT ITEMS IN THIS INSTRUMENT.

**PUC005/( R\_FNAME)/(R\_MNAME)/(R\_LNAME).** WHAT IS THE MOTHER'S NAME?

_____ FIRST NAME (M_FNAMEP)	_____ MIDDLE NAME (R_MNAME)	_____ LAST NAME (R_LNAME)
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DON'T KNOW..... -2

**INTERVIEWER INSTRUCTIONS:**

- CONFIRM SPELLING.
- IF RESPONDENT REFUSES TO PROVIDE FIRST NAME, ASK FOR INITIALS.

**PUC010/(CHILD\_NAME\_A).** WHAT IS CHILD A'S NAME?

\_\_\_\_\_  
CHILD A NAME

DON'T KNOW.....-2

**PUC020/(CHILD\_NAME\_B).** CHILD B'S NAME

\_\_\_\_\_  
CHILD B NAME

DON'T KNOW.....-2

NOT APPLICABLE.....-7

**PUC030/(MOTHER\_DOB\_A).** MOTHER'S DATE OF BIRTH:

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE MOTHER'S DATE OF BIRTH.
- RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

MONTH: |\_\_|\_\_|

M M  
 DAY: |\_\_|\_\_|  
 D D  
 YEAR: |\_\_|\_\_|\_\_|\_\_|  
 Y Y Y Y

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

**PROGRAMMER INSTRUCTIONS:**

- 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.

**PUC040/(CHILD\_A\_DOB).** CHILD A'S DATE OF BIRTH:

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD CHILD A'S DATE OF BIRTH.
- RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

MONTH: |\_\_|\_\_|  
 M M  
 DAY: |\_\_|\_\_|  
 D D  
 YEAR: |\_\_|\_\_|\_\_|\_\_|  
 Y Y Y Y

REFUSED..... -1  
 DON'T KNOW..... -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 YEAR IS < 2012.
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.

**PUC050/(TIME\_BIRTH\_CHILDA).** TIME OF CHILD A'S BIRTH:

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE TIME AS HH:MM.
- BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY.







**DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE TIME AS HH:MM.
- BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY.

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

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

**PUC160/(TIME\_PLAC\_COLLECT\_UNIT).** UNIT OF TIME OF COLLECTION OF PLACENTA AND CORD – AM/PM

**DATA COLLECTOR INSTRUCTIONS:**

- MARK THE BOX TO CHOOSE “AM” OR “PM” FOR TIME OF COLLECTION.

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

**PUC170/(DATE\_PLACED\_8C).** DATE THE PLACENTA AND CORD WERE PLACED AT 2-8°C:

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD DATE PLACENTA AND CORD PLACED AT 2-8°C.
- RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

MONTH:

|\_|\_|  
M M

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

DAY:

|\_|\_|  
D D

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

YEAR:

|\_|\_|\_|\_|  
Y Y Y Y

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

**PUC180/(TIME\_PLACED\_8C).** TIME THE PLACENTA AND CORD WERE PLACED AT 2-8°C:

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE TIME AS HH:MM.
- BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY.

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

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

**PUC190/(TIME\_PATHLAB\_RECEIVE\_UNIT).** UNIT OF TIME THE PLACENTA AND CORD WERE PLACED AT 2-8°C – AM/PM:

**DATA COLLECTOR INSTRUCTIONS:**

- MARK THE BOX TO CHOOSE “AM” OR “PM” FOR TIME PLACENTA AND CORD WERE PLACED AT 2-8°C.

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

**PUC200/(SPECIMEN\_FRESH).** IS THE PLACENTA SPECIMEN FRESH OR FIXED?

FRESH.....1 (**SPEC\_TYPE\_COLLECT**)  
FIXED .....2

**PUC210/(REASON\_SPEC\_FIXED).** WHICH REASON BEST DESCRIBES WHY THE SPECIMEN WAS FIXED?

PLACENTA WAS NOT RELEASED  
WITHIN 5 DAYS OF DELIVERY.....1  
TISSUE FIXED AS PART OF  
PATHOLOGY LAB EVALUATION.....2

**PUC220/(DATE\_SPEC\_FIXED).** DATE THE SPECIMEN WAS FIXED:

**DATA COLLECTOR INSTRUCTIONS:**

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

MONTH:

|\_|\_|  
M M

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

DAY:

|\_|\_|  
D D

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

YEAR:

|\_|\_|\_|  
Y Y Y Y

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

**PUC230/(TIME\_SPEC\_FIXED).** TIME THE SPECIMEN WAS FIXED:

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE TIME AS HH:MM.
- BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY.

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

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

**PUC240/(TIME\_SPEC\_FIXED\_UNIT).** UNIT OF TIME THE SPECIMEN WAS FIXED – AM/PM:

**DATA COLLECTOR INSTRUCTIONS:**

- MARK THE BOX TO CHOOSE “AM” OR “PM” FOR TIME SPECIMEN FIXED.

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

**PUC250/(SPEC\_TYPE\_COLLECT).** WHAT KIND OF SPECIMEN WAS COLLECTED?

WHOLE PLACENTA.....1 **(TIME\_STAMP\_PUC\_ET)**  
PARTIAL PLACENTAL TISSUE.....2

**PUC260/(PARTIAL\_SAMP\_LOC).** PLEASE INDICATE THE LOCATION WHERE SAMPLES WERE TAKEN:

TOP-RIGHT SIDE.....1  
TOP-LEFT SIDE.....2  
RIGHT SIDE.....3  
LEFT SIDE.....4  
BOTTOM-RIGHT SIDE.....5  
BOTTOM-LEFT SIDE.....6  
MIDDLE.....7

**PUC270/(PT\_CORD\_INSERT).** PLEASE INDICATE THE POINT OF CORD INSERTION:

TOP-RIGHT SIDE.....1  
TOP-LEFT SIDE.....2  
RIGHT SIDE.....3  
LEFT SIDE.....4  
BOTTOM-RIGHT SIDE.....5  
BOTTOM-LEFT SIDE.....6  
MIDDLE.....7

**PUC280/(LOC\_ACCESSORY\_LOBE).** PLEASE INDICATE THE LOCATION OF ANY ACCESSORY LOBES (IF APPLICABLE):

TOP-RIGHT SIDE.....1  
TOP-LEFT SIDE.....2  
RIGHT SIDE.....3  
LEFT SIDE.....4  
BOTTOM-RIGHT SIDE.....5  
BOTTOM-LEFT SIDE.....6

MIDDLE.....7  
NOT APPLICABLE.....-7

**PUC290/(DISK\_OUTLINE\_IRREG).** PLEASE INDICATE THE LOCATION OF ANY IRREGULARITIES OF THE DISK OUTLINE (IF APPLICABLE):

TOP-RIGHT SIDE.....1  
TOP-LEFT SIDE.....2  
RIGHT SIDE.....3  
LEFT SIDE.....4  
BOTTOM-RIGHT SIDE.....5  
BOTTOM-LEFT SIDE.....6  
NOT APPLICABLE.....-7

**PUC300/(DATA\_COLLECTOR\_ID).** DATA COLLECTOR ID?

SPECIFY \_\_\_\_\_

**(TIME\_STAMP\_PUC\_ET) PROGRAMMER INSTRUCTION:**

- INSERT DATE/TIME STAMP.