OMB #: 0925-0593 OMB Expiration Date: 8/31/2014 Placenta Instrument, Phase 2g OMB Specification



## **Placenta Instrument**

Event Category:	Time-Based
Event:	Birth
Administration:	N/A
Instrument Target:	Biological Mother
Instrument Respondent:	Data Collector
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:	0 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.

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## **Placenta Instrument**

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## **Placenta 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 CHARACTE RS PERMITTED	DATA TYPE	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	CHARACTER	
UNIT AND PHONE FIELDS	10	CHARACTER	
_OTH AND COMMENT FIELDS	255	CHARACTER	Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	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	<ul> <li>DISPLAY AS MM/DD/YYYY</li> <li>STORE AS YYYY-MM-DD</li> <li>HARD EDITS: MM MUST EQUAL 01 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 DESIGNATI ON	NUMERIC	<ul> <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 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.** 

## PLACENTA INSTRUMENT

(TIME\_STAMP\_PI\_ST).

## PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT ID (P\_ID) FOR THE CHILD.

## DATA COLLECTOR INSTRUCTIONS

- IF NON-FIXED PLACENTA(S) ARE AVAILABLE FROM THE PARTICIPANT'S DELIVERY, NCS DATA COLLECTORS OR HOSPITAL STAFF WILL WEIGH AND PHOTOGRAPH THE PLACENTA AND ATTACHED UMBILICAL CORD(S).
- A CAMERA AND SCALE AS WELL AS SUPPLIES TO DISSECT, PRESERVE, AND TRANSPORT TWO SECTIONS OF NON-FIXED PLACENTA ARE NEEDED.
- FOLLOW THE INSTRUCTIONS IN THE NCS BIOSPECIMEN PLACENTA PROCEDURE.
- COMPLETE THIS INSTRUMENT WITH THE BEST INFORMATION AVAILABLE.

PI02000. TIME OF CHILD'S BIRTH:

(CHILD\_BIRTH\_TIME) |\_\_\_| |:|\_\_|

## (CHILD\_BIRTH\_TIME\_UNIT)

Label	Code	Go To
AM	1	
РМ	2	

## PI03000. TIME OF PLACENTA DELIVERY

(PLACENTA\_DELIVERY\_TIME) |\_\_\_|:|\_\_\_|

H H M M

Label	Code	Go To
DON'T KNOW	-2	PLAC_COLLECT

## (PLACENTA\_DELIVERY\_TIME\_UNIT)

Label	Code	Go To
AM	1	
РМ	2	

## PI04000/(PLAC\_COLLECT). WAS THE PLACENTA COLLECTED?

Label	Code	Go To
YES	1	
NO	2	

**PI05000/(REASON\_PLAC\_NOCOLLECT).** CHOOSE THE PRIMARY REASON THAT BEST DESCRIBES WHY THE PLACENTA WAS NOT COLLECTED:

Label	Code	Go To
PARENT/GUARDIAN	1	SPECIMEN_DC_COMMENTS
REFUSAL		
NOT PART OF HOSPITAL	2	SPECIMEN_DC_COMMENTS
PROCEDURES		
FRESH PLACENTA WAS	3	REASON_FREPLAC_NOAVAI
NOT AVAILABLE		L
OTHER	-5	

## PI06000/(REASON\_PLAC\_NOCOLLECT\_OTH).

SPECIFY:

PROGRAMMER INSTRUCTIONS
GO TO SPECIMEN\_DC\_COMMENTS.

**PI06010/(REASON\_FREPLAC\_NOAVAIL).** WHY WAS THERE NO FRESH PLACENTA AVAILABLE?

Label	Code	Go To
PLACENTA WAS SENT TO	1	SPECIMEN_DC_COMMENT
PATHOLOGY WHERE		S
TISSUE WAS FIXED		
OTHER	-5	
DON'T KNOW	-2	SPECIMEN_DC_COMMENT
		S

PI06020/(REASON\_FREPLAC\_NOAVAIL\_OTH).

SPECIFY:

PROGRAMMER INSTRUCTIONS

• GO TO **SPECIMEN\_DC\_COMMENTS**.

**PI06030/(PLAC\_RESEARCH\_PRIOR).** WAS THE PLACENTA USED FOR CLINICAL OR NON-NCS RESEARCH PURPOSES PRIOR TO BEING ASSESSED BY NCS DATA COLLECTOR?

Label	Code	Go To
YES, CLINICAL USE	1	PLAC_PROCESS_WHERE
YES, NON-NCS RESEARCH PURPOSES	2	PLAC_PROCESS_WHERE
NO	3	PLAC_PROCESS_WHERE
OTHER USE	-5	
DON'T KNOW	-2	PLAC_PROCESS_WHERE

PI06040/(PLAC\_RESEARCH\_PRIOR\_OTH).

SPECIFY:

**PI06050/(PLAC\_PROCESS\_WHERE).** WHERE DID THE PROCESSING OF THE PLACENTA OCCUR?

Label	Code	Go To
HOSPITAL	1	PLAC_WHO_COLLECT
SPSC	2	SPECIMEN_0_ID
OTHER	-5	

#### PI06060/(PLAC\_PROCESS\_WHERE\_OTH).

SPECIFY:

PI06070/(SPECIMEN\_0\_ID). RECORD THE NCS SPECIMEN ID OF THE FULL PLACENTA

#### **PROGRAMMER INSTRUCTIONS**

- GO TO FULL\_PLAC\_COMMENTS.

## PI06100/(PLAC\_WHO\_COLLECT). WHO COLLECTED THE SPECIMEN?

Label	Code	Go To
HOSPITAL STAFF	1	
NCS STAFF	2	
DON'T KNOW	-2	

PI12000. DATE THE PLACENTA WAS WEIGHED, PHOTOGRAPHED AND/OR SECTIONED:

## (PLACENTA\_WEIGH\_MM) |\_\_\_|

M M

Label	Code	Go To
NOT APPLICABLE	-7	PI13000

(PLACENTA\_WEIGH\_DD) |\_\_\_|

D D

(PLACENTA\_WEIGH\_YYYY) |\_\_\_|

**PI13000.** TIME THE PROCEDURES TO WEIGH AND/OR PHOTOGRAPH PLACENTA BEGAN:

## (PLACENTA\_WEIGH\_TIME) |\_\_\_\_|:|\_\_\_\_|

H H M M

Label	Code	Go To
NOT APPLICABLE	-7	PLACENTA_WEIGHT

Y Y Y Y

## (PLACENTA\_WEIGH\_TIME\_UNIT)

Label	Code	Go To
AM	1	
РМ	2	

## PI14000/(PLACENTA\_WEIGHT). |\_\_\_| g

Label	Code	Go To
UNABLE TO WEIGH	-8	

## **PROGRAMMER INSTRUCTIONS**

• IF PLACENTA\_WEIGHT = -8, GO TO PLACENTA\_WEIGHT\_OTH.

• OTHERWISE, GO TO ?PLACENTA PHOTO?.

PI15000/(PLACENTA\_WEIGHT\_OTH). SPECIFY WHY THE PLACENTA WAS NOT WEIGHED:

PI16000/(PLACENTA\_PHOTO). WAS THE PLACENTA PHOTOGRAPHED?

Label	Code	Go To
YES	1	PLACENTA_SECTIONED
NO	2	

PI17000/(PLACENTA\_PHOTO\_OTH). SPECIFY WHY THE PLACENTA WAS NOT PHOTOGRAPHED:

PI18000/(PLACENTA\_SECTIONED). WAS THE PLACENTA SECTIONED?

Label	Code	Go To
YES	1	PI20000
NO	2	

PI19000/(PLACENTA\_SECTIONED\_OTH). SPECIFY WHY THE PLACENTA WAS NOT SECTIONED: \_\_\_\_\_

PROGRAMMER INSTRUCTIONS
 GO TO SPECIMEN\_DC\_COMMENTS.

PI20000. TIME THE PROCEDURES TO SECTION THE PLACENTA BEGAN:

(PLACENTA\_SECTION\_TIME) | | | | ||

H H M M

## (PLACENTA\_SECTION\_TIME\_UNIT)

Label	Code	Go To
AM	1	
РМ	2	

**PI21000/(PARTIAL\_SAMP\_LOC).** PLEASE INDICATE THE LOCATION WHERE THE SAMPLE WAS TAKEN:

Label	Code	Go To
TOP-RIGHT SIDE	1	PLAC_SECTION_TWO
TOP-LEFT SIDE	2	PLAC_SECTION_TWO
RIGHT SIDE	3	PLAC_SECTION_TWO
LEFT SIDE	4	PLAC_SECTION_TWO
BOTTOM-RIGHT SIDE	5	PLAC_SECTION_TWO
BOTTOM-LEFT SIDE	6	PLAC_SECTION_TWO
MIDDLE	7	PLAC_SECTION_TWO
OTHER	-5	

PI22000/(PARTIAL\_SAMP\_LOC\_OTH).

SPECIFY:

**PI23000/(PLAC\_SECTION\_TWO).** WAS THE PLACENTA SECTION CUT INTO TWO PIECES?

Label	Code	Go To
YES	1	SPECIMEN_1_ID
NO	2	

PI24000/(PLAC\_SECTION\_TWO\_OTH).

SPECIFY

NOT:

WHY

## PI25000/(SPECIMEN\_1\_ID). RECORD THE NCS SPECIMEN ID

#### PROGRAMMER INSTRUCTIONS

- DISPLAY HARD EDIT IF SPECIMEN ID IS NOT FORMATTED AS TWO ALPHA, SEVEN NUMERIC CHARACTERS DASH TWO ALPHA, TWO NUMERIC CHARACTERS (AA#######-AA##)
- IF PLAC\_SECTION\_TWO = 1, GO TO SPECIMEN\_2\_ID.
- OTHERWISE, GO TO PI27000.

PI26000/(SPECIMEN_2_ID).	RECORD	THE	NCS	SPECIMEN	ID
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## PROGRAMMER INSTRUCTIONS

 DISPLAY HARD EDIT IF SPECIMEN ID IS NOT FORMATTED AS TWO ALPHA, SEVEN NUMERIC CHARACTERS DASH TWO ALPHA, TWO NUMERIC CHARACTERS (AA#######-AA##)

## PI27000. TIME THE PROCEDURES TO SECTION THE PLACENTA ENDED

## (PLACENTA\_SECTION\_END\_TIME) | | | || ||

H H M M

## (PLACENTA\_SECTION\_END\_TIME\_UNIT)

Label	Code	Go To
AM	1	
РМ	2	

**PI30000/(SPECIMEN\_DC\_COMMENTS).** DO YOU HAVE ANY COMMENTS ABOUT THE PLACENTA COLLECTION THAT WERE NOT ALREADY NOTED?

Label	Code	Go To
YES	1	
NO	2	TIME_STAMP_PI_ET

PI31000/(SPECIMEN\_DC\_COMMENTS\_OTH). PLACENTA COLLECTION COMMENTS NOT ALREADY NOTED.

SPECIFY:

## DATA COLLECTOR INSTRUCTIONS

• IF THERE WERE ANY PLACENTA COLLECTION COMMENTS NOT ALREADY NOTED, ENTER THEM IN THE SPACE PROVIDED.

## **PROGRAMMER INSTRUCTIONS**

• GO TO TIME\_STAMP\_PI\_ET.

**PI32000/(FULL\_PLAC\_COMMENTS).** DO YOU HAVE ANY COMMENTS ABOUT THE FULL PLACENTA COLLECTION THAT WERE NOT ALREADY NOTED?

Label	Code	Go To
YES	1	
NO	2	TIME_STAMP_PI_ET

**PI33000/(FULL\_PLAC\_COMMENTS\_OTH).** FULL PLACENTA COLLECTION COMMENTS NOT ALREADY NOTED. SPECIFY:

#### DATA COLLECTOR INSTRUCTIONS

• IF THERRE WERE ANY FULL PLACENTA COLLECTION COMMENTS NOT ALREADY NOTED, ENTER THEM IN THE SPACE PROVIDED.

## (TIME\_STAMP\_PI\_ET).

#### **PROGRAMMER INSTRUCTIONS**

- INSERT DATE/TIME STAMP
- IF PLAC\_COLLECT = 2, GO TO TIME\_STAMP\_PFP\_ET.
- IF PLAC\_COLLECT = 1, GO TO TIME\_STAMP\_PFP\_ST.

## PREPARATION FOR PLACENTA TRANSPORT

(TIME\_STAMP\_PFP\_ST).

## PROGRAMMER INSTRUCTIONS INSERT DATE/TIME STAMP

## **PFP01000/(COLD\_TEMP\_MEASURE).** TEMPERATURE OF REFRIGERATED CHAMBER

## DATA COLLECTOR INSTRUCTIONS

- PREPARE THE PLACENTA SPECIMEN FOR TRANSPORT.
- IF ABLE TO MEASURE TEMPERATURE, THEN SELECT "TEMPERATURE." ENTER THE TEMPERATURE OF THE DIGITAL THERMOMETER IN THE TRANSPORT COOLER AT THE TIME THE DATA COLLECTOR PUTS THE SPECIMEN IN THE COOLER.
- IF NOT ABLE TO MEASURE TEMPERATURE, THEN SELECT "NOT ABLE TO MEASURE" AND THE REASON THE TEMPERATURE COULD NOT BE RECORDED.
- IF THERE ARE NOT ANY TUBES THAT REQUIRE REFRIGERATED TRANSPORT TEMPERATURES, THEN SELECT "NOT APPLICABLE."

Label	Code	Go To
TEMPERATURE	1	
NOT ABLE TO MEASURE -	2	
THERMOMETER BROKEN		
NOT ABLE TO MEASURE -	3	
THERMOMETER NOT		
AVAILABLE		
NOT ABLE TO MEASURE -	-5	
OTHER		
NOT APPLICABLE	-7	

PFP02000/(COLD\_TEMP\_MEASURE\_OTH).

SPECIFY:

# PROGRAMMER INSTRUCTIONS GO TO TRANSPORT COMMENT.

## PFP03000. RECORD TEMPERATURE OF REFRIGERATED CHAMBER

## DATA COLLECTOR INSTRUCTIONS

 RECORD THE TEMPERATURE OF THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.

## (COLD\_TEMP) ENTER TEMPERATURE IN DEGREES CELSIUS

0°[\_\_\_\_\_.

(COLD\_TEMP\_POSNEG) RECORD IF THE TEMPERATURE IS A POSITIVE OR NEGATIVE VALUE

## DATA COLLECTOR INSTRUCTIONS

- IF TEMPERATURE IS ZERO OR ABOVE, RECORD "POSITIVE"
- IF TEMPERATURE IS BELOW ZERO, RECORD "NEGATIVE"

Label	Code	Go To
POSITIVE	1	
NEGATIVE	2	

#### **PROGRAMMER INSTRUCTIONS**

- SOFT EDIT: DISPLAY SOFT EDIT IF **COLD\_TEMP** ≥ 10.0 OR ≤ 0.0
- SOFT EDIT: DISPLAY SOFT EDIT IF NO VALUE ENTERED IN THE FIELD
- FOLLOWING THE DECIMAL POINT IN COLD\_TEMP.

## PFP04000/(TRANSPORT\_COMMENT). TRANSPORT COMMENT

Label	Code	Go To
NO COMMENTS	1	TIME_STAMP_PFP_ET
COMMENT	2	

# PFP05000/(TRANSPORT\_COMMENT\_OTH).

# DATA COLLECTOR INSTRUCTIONS

ENTER ANY TRANSPORT COMMENT.

## (TIME\_STAMP\_PFP\_ET).

## PROGRAMMER INSTRUCTIONS

INSERT DATE/TIME STAMP