OMB#: 0925-0593 OMB Expiration Date: 8/31/2014 Biospecimen Cord Blood Instrument Phase 2f



Biospecimen Cord Blood Instrument

Event:	Birth
Participant:	Child
Domain:	Biospecimen
Type of Document:	Data Collection Instrument
Recruitment Groups:	EH, PB, HI, PBS
Version:	3.0
Release:	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 Cord Blood Instrument

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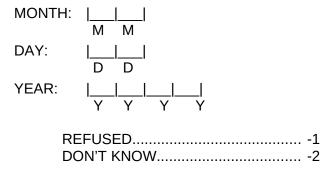
(TIME_STAMP_1). PROGRAMMER INSTRUCTION:

• INSERT DATE/TIME STAMP.

CB001/(PERSON_DOB). MOTHER'S DATE OF BIRTH

DATA COLLECTOR INSTRUCTION:

 RECORD THE MOTHER'S DATE OF BIRTH. THE TWO DIGIT MONTH, THE TWO DIGIT DAY, AND THE FOUR DIGIT YEAR SHOULD BE RECORDED.



PROGRAMMER INSTRUCTIONS:

- FORMAT PERSON DOB 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.
- SOFT EDIT: INCLUDE SOFT EDIT IF YEAR < 1960.

CB002/(CHILD_DOB). CHILD'S DATE OF BIRTH

DATA COLLECTOR INSTRUCTION:

• RECORD THE CHILD'S DATE OF BIRTH. THE TWO DIGIT MONTH, THE TWO DIGIT DAY, AND THE FOUR DIGIT YEAR SHOULD BE RECORDED.

PROGRAMMER INSTRUCTIONS:

- FORMAT CHILD_DOB 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.
- SOFT EDIT: INCLUDE SOFT EDIT IF YEAR < 2011.

CB003/(CORD_BIRTH_HR)/(CORD_BIRTH_MIN)/(CORD_BIRTH_UNIT). TIME OF CHILD'S BIRTH: HOUR\TIME OF CHILD'S BIRTH: MINUTE\TIME OF CHILD'S BIRTH AM/PM

DATA COLLECTOR INSTRUCTION:

RECORD THE TIME OF THE CHILD'S BIRTH. 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 CHILD WAS BORN AT 2:05 PM RECORD "02:05" AND
CHOOSE "PM".

HOUR:	<u> </u>	
MINUTES:		
	JSED	

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF CORD_BIRTH_HR OR
 CORD_BIRTH_MIN IS NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY).
- HARD EDIT: INCLUDE HARD EDIT IF **CORD_BIRTH_HR** IS NOT BETWEEN 01 AND 12.
- HARD EDIT: INCLUDE HARD EDIT IF **CORD_BIRTH_MIN** IS NOT BETWEEN 00 AND 59.
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.

CB004/(CHILD_SEX). CHILD'S GENDER

DATA COLLECTOR INSTRUCTION:

• SELECT THE CHILD'S GENDER.

MALE	1
FEMALE	2
BOTH	3
REFUSED	-1
DON'T KNOW	-2

CB005/(CORD_COLLECTION). CORD BLOOD COLLECTION STATUS

Was the cord blood collected for the NCS?

YES	1	(CORD_COLLECT_DATE)
NO	2	

CB006/(CORD_NOTCOL_COMMENT). CORD BLOOD NOT COLLECTED REASON

Please choose the one reason that best describes why the blood was not collected.

DATA COLLECTOR INSTRUCTIONS:

- MARK ONLY ONE REASON THAT CORD BLOOD WAS NOT COLLECTED.
- CHOOSE "PARENT CHOSE TO BANK" TO INDICATE PARENTS HAVE CHOSEN TO PARTICIPATE IN A PRIVATE CORD BLOOD BANKING PROGRAM.
- CHOOSE "OTHER BANKING PROGRAM" TO INDICATE THAT PARENTS HAVE CHOSEN TO PARTICIPATE IN A PUBLIC CORD BLOOD BANKING PROGRAM.

PARENTS CHOSE TO BANK	1	(TIME_STAMP_2)
NEED FOR CLINICAL PURPOSES	2	(TIME_STAMP_2)
OTHER BANKING PROGRAM	3	(TIME_STAMP_2)
PARENT/GUARDIAN REFUSAL	4	(TIME_STAMP_2)
QUANTITY NOT SUFFICIENT	5	(TIME_STAMP_2)
DEFECTIVE COLLECTION EQUIPMENT	6	(TIME_STAMP_2)
NO TIME	7	(TIME_STAMP_2)
PRECIPITOUS DELIVERY	8	(TIME_STAMP_2)
STUDY STAFF NOT PRESENT AT DELIVERY	9	(TIME_STAMP_2)
NCS NOT NOTIFIED OF BIRTH IN TIME	10	(TIME_STAMP_2)
PARTICIPANT NOT IDENTIFIED PRIOR TO BIRTH	11	(TIME_STAMP_2)
OTHER	5	

CB006A/(CORD_NOTCOL_OTH). CORD BLOOD NOT COLLECTED

DATA COLLECTOR INSTRUCTION: IF THE CORD BLOOD WAS NOT COLLECTED FOR A REASON NOT LISTED IN THE PREVIOUS QUESTION, TYPE IN THE REASON BELOW.

SPECIFY:	(TIME_STAMP_2
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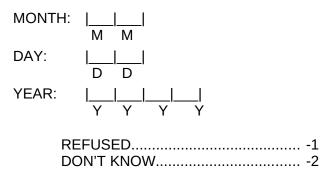
PROGRAMMER INSTRUCTION:

• LIMIT TEXT TO 255 CHARACTERS.

CB007/(CORD_COLLECT_DATE). DATE CORD BLOOD COLLECTED

DATA COLLECTOR INSTRUCTION:

 RECORD THE DATE THE CORD BLOOD WAS COLLECTED. THE TWO DIGIT MONTH, THE TWO DIGIT DAY, AND THE FOUR DIGIT YEAR SHOULD BE RECORDED.



PROGRAMMER INSTRUCTIONS:

- FORMAT CORD COLLECT 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.
- SOFT EDIT: INCLUDE SOFT EDIT IF YEAR < 2011.

CB008/(CORD_COLLECT_HR)/(CORD_COLLECT_MIN)/(CORD_COLLECT_UNIT). TIME OF CORD BLOOD COLLECTION: HOUR\TIME OF CORD BLOOD COLLECTION: MINUTE\
TIME OF CORD BLOOD COLLECTION AM/PM

DATA COLLECTOR INSTRUCTION:

 RECORD THE TIME OF THE CORD BLOOD COLLECTION BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO CHOOSE "AM" OR "PM". FOR EXAMPLE, IF THE CHILD WAS BORN AT 2:05 PM RECORD "02:05" AND CHOOSE "PM".
HOUR: _ H H
MINUTES:
AM
PROGRAMMER INSTRUCTIONS: • HARD EDIT: INCLUDE HARD EDIT IF CORD_COLLECT_HR OR CORD_COLLECT_MIN IS NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
 HARD EDIT: INCLUDE HARD EDIT IF CORD_COLLECT_HR IS NOT BETWEEN 01 AND 12.
 HARD EDIT: INCLUDE HARD EDIT IF CORD_COLLECT_MIN IS NOT BETWEEN 00 AND 59.
 HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
CB009/(CORD_WHERE_COLLECT). Where was the sample collected?
DATA COLLECTOR INSTRUCTIONS: • IF THE CORD BLOOD WAS COLLECTED PRIOR TO DELIVERY OF THE PLACENTA, CHOOSE "IN UTERO".
 IF THE CORD BLOOD WAS COLLECTED AFTER DELIVERY OF THE PLACENTA, CHOOSE "EX UTERO".
IN UTERO 1 EX UTERO 2
CB010/(CORD_DELIVERY). What type of delivery was performed?

• IF THE I	ISTRUCTIONS: DELIVERY WAS A VAGINAL DELIVERY CHOOSE "VAGINAL."
• IF THE	DEIVERY WAS CESAREAN (C-SECTION) CHOOSE "CESAREAN."
_	L 1 EAN 2
CB010A/(CORD_METI	HOD). What method was used to collect the cord blood?
VACUTAINER	OM CORD INTO CORD BLOOD BAG OR TUBES
CB010B/(CORD_METI	HOD_OTH). CORD BLOOD COLLECTION METHOD
DATA COLLECTOR IN	ISTRUCTION:
	ORD BLOOD WAS NOT COLLECTED DIRECTLY INTO CORD BLOOD VACUTAINER TUBES, ENTER THE COLLECTION METHOD BELOW
SPECIFY	
PROGRAMMER INSTI	RUCTION:
• LIMIT TEX	T TO 255 CHARACTERS.
CB011/(CORD_CONT	AINER). In what type of container was the cord blood collected for NCS?
CORD STICK V	BAG WITH HEPARIN
CB012/(COLLECTION	_TYPE).
BOTH TUB o DISPLA	ROUGH COLLECTION_TYPE, SPECIMEN_ID, TUBE_STATUS FOR

=2; DISPLAY "LAVENDER CAP"

_TYPE =3; DISPLAY "RED CAP"

• IF FIRST CYCLE OF THE LOOP, THEN COLLECTION_TYPE

• IF SECOND CYCLE OF THE LOOP, THEN COLLECTION

CB013/(SPECIMEN_ID) MANUAL ENTRY OF SPECIMEN_ID

■ IF CORD CONTAINER=3:

DATA COLLECTOR INSTRUCTIONS:

- RECORD THE SPECIMEN_ID PRINTED ON THE LABEL OF THE CORD BLOOD COLLECTION CONTAINER.
 - o FOR **COLLECTION_TYPE** =1 (CORD BLOOD BAG), FORMAT SHOULD BE AA######-CB##
 - o FOR **COLLECTION_TYPE** =2 (LAVENDAR CAP), FORMAT SHOULD BE AA######-CL##
 - o FOR **COLLECTION_TYPE** =3 (RED CAP), FORMAT SHOULD BE AA######-CS##

PROGRAMMER INSTRUCTIONS

- DISPLAY CORRECT COLLECTION_TYPE DESCRIPTION IN BRACKETS AND FORMAT FOR SPECIMEN ID FOR EACH LOOP:
 - 0 IF COLLECTION_TYPE=1, DISPLAY "CORD BLOOD BAG"
 - o IF COLLECTION_TYPE=2, DISPLAY "LAVENDER CAP"
 - o IF COLLECTION TYPE=3, DISPLAY "RED CAP"
- HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT:
 - o AA # # # # # # #-CB## **COLLECTION TYPE** = 1, CORD BLOOD BAG.
 - o AA######-CL## FOR COLLECTION TYPE= 2, LAVENDER CAP
 - o AA#######-CS## FOR COLLECTION TYPE=3 RED CAP
- IF COLLECTION_TYPE=1 GO TO TIME_STAMP_2

CB014/(TUBE STATUS). CORD BLOOD TUBE COLLECTION STATUS:

DATA COLLECTOR INSTRUCTIONS:

- ENTER STATUS OF COLLECTION_TYPE.
- SELECT "FULL DRAW" TO INDICATE THAT THE BLOOD TUBE WAS FILLED TO AT LEAST 1/2 OF THE DESIRED CAPACITY. DESIRED CAPACITY IS DEFINED AS FILLED TO THE FILL LINE INDICATED ON THE BLOOD TUBE LABEL.
- SELECT "SHORT DRAW" TO INDICATE THAT THE BLOOD TUBE WAS FILLED TO LESS THAN 1/2 OF THE DESIRED CAPACITY.
- SELECT "NO DRAW" TO INDICATE THAT THE BLOOD TUBE WAS NOT COLLECTED.

FULL DRAW	1
SHORT DRAW	2
NO DRAW	3

PROGRAMMER INSTRUCTIONS:

- DISPLAY CORRECT DESCRIPTION IN BRACKETS AND FORMAT FOR **SPECIMEN_ID** FOR EACH LOOP:
 - o IF COLLECTION_TYPE=2 DISPLAY "LAVENDER CAP"
 - o IF **COLLECTION_TYPE**=3 DISPLAY "RED CAP"

CB015/(OVERALL	COMMENTS).
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CB015/(OVERALL_COMMENTS).
DATA COLLECTOR INSTRUCTION: DO YOU HAVE ANY COMMENTS ABOUT THE CORD BLOOD COLLECTION THAT WERE NOT ALREADY NOTED?
YES
CB016/(OVERALL_COMMENTS_OTH). CORD BLOOD COLLECTION COMMENTS NOT ALREADY NOTED
 DATA COLLECTOR INSTRUCTION: IF THERE WERE ANY CORD BLOOD COLLECTION COMMENTS NOT ALREADY NOTED, ENTER THEM BELOW.
SPECIFY

PROGRAMMER INSTRUCTION:

• LIMIT TEXT TO 255 CHARACTERS.

(TIME_STAMP_2). PROGRAMMER INSTRUCTION:

INSERT DATE/TIME STAMP.