



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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Biospecimen Cord Blood Instrument

(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.

MONTH: |__|__|
 M M
DAY: |__|__|
 D D
YEAR: |__|__|__|__|
 Y Y Y Y

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

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.

MONTH: |__|__|
 M M
DAY: |__|__|
 D D
YEAR: |__|__|__|__|
 Y Y Y Y

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

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: |_|_|
 H H

MINUTES: |_|_|
 M M

AM..... 1

PM..... 2

REFUSED..... -1

DON'T KNOW..... -2

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)

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.

MONTH: |__|__|
 M M

DAY: |__|__|
 D D

YEAR: |__|__|__|__|
 Y Y Y Y

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

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: |_|_|
 M M

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

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?

DATA COLLECTOR INSTRUCTIONS:

- IF THE DELIVERY WAS A VAGINAL DELIVERY CHOOSE "VAGINAL."
- IF THE DEIVERY WAS CESAREAN (C-SECTION) CHOOSE "CESAREAN."

VAGINAL..... 1
CESAREAN 2

CB010A/(CORD_METHOD). What method was used to collect the cord blood?

DIRECTLY FROM CORD INTO CORD BLOOD BAG OR
VACUTAINER TUBES..... 1 **(CORD_CONTAINER)**
OTHER, SPECIFY.....-5

CB010B/(CORD_METHOD_OTH). CORD BLOOD COLLECTION METHOD

DATA COLLECTOR INSTRUCTION:

- IF THE CORD BLOOD WAS NOT COLLECTED DIRECTLY INTO CORD BLOOD BAG OR VACUTAINER TUBES, ENTER THE COLLECTION METHOD BELOW

SPECIFY _____

PROGRAMMER INSTRUCTION:

- **LIMIT TEXT TO 255 CHARACTERS.**

CB011/(CORD_CONTAINER). In what type of container was the cord blood collected for NCS?

CORD BLOOD BAG WITH HEPARIN..... 1
CORD STICK VACUTAINER TUBES..... 2
OTHER VACUTAINER TUBES..... 3

CB012/(COLLECTION_TYPE).

PROGRAMMER INSTRUCTION:

- LOOP THROUGH **COLLECTION_TYPE**, **SPECIMEN_ID**, **TUBE_STATUS** FOR BOTH TUBES
 - o DISPLAY CORRECT **COLLECTION_TYPE** FOR EACH LOOP:
 - IF **CORD_CONTAINER** = 1 OR 2, THEN **COLLECTION_TYPE=1**; DISPLAY "CORD BLOOD BAG"
 - IF **CORD_CONTAINER=3**:
 - IF FIRST CYCLE OF THE LOOP, THEN **COLLECTION_TYPE =2**; DISPLAY "LAVENDER CAP"
 - IF SECOND CYCLE OF THE LOOP, THEN **COLLECTION_TYPE =3**; DISPLAY "RED CAP"

CB013/(SPECIMEN_ID) MANUAL ENTRY OF SPECIMEN_ID

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:
 - o 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).

DATA COLLECTOR INSTRUCTION: DO YOU HAVE ANY COMMENTS ABOUT THE CORD BLOOD COLLECTION THAT WERE NOT ALREADY NOTED?

YES.....1
NO.....2 **(TIME_STAMP_2)**

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.