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Biospecimen Cord Blood Instrument

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| --- | --- |
| **Event:** | Birth |
| **Participant:** | Child |
| **Domain:** | Biospecimen |
| **Type of Document:** | Data Collection Instrument |
| **Recruitment Groups:** | EH, PB, HI, PBS |
| **Version:** | 3.0 |
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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
  + 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.
  + FOR **COLLECTION\_TYPE** =1 (CORD BLOOD BAG), FORMAT SHOULD BE AA#######-CB##
  + FOR **COLLECTION\_TYPE** =2 (LAVENDAR CAP), FORMAT SHOULD BE AA#######-CL##
  + 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:
  + IF **COLLECTION\_TYPE**=1, DISPLAY “CORD BLOOD BAG”
  + IF **COLLECTION\_TYPE**=2, DISPLAY “LAVENDER CAP”
  + IF **COLLECTION\_TYPE**=3, DISPLAY “RED CAP”
* HARD EDIT: INCLUDE HARD EDIT IF FORMAT IS NOT:
  + AA # # # # # # #-CB## **COLLECTION\_TYPE** = 1, CORD BLOOD BAG.
  + AA # # # # # # #-CL## FOR **COLLECTION\_TYPE**= 2, LAVENDER\_CAP
  + 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:
  + IF **COLLECTION\_TYPE**=2 DISPLAY “LAVENDER CAP”
  + 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.