OMB #: 0925-0593 OMB Expiration Date: 07/31/ 2013 Biospecimen Child Blood Instrument, Phase 2e



# **Biospecimen Child Blood Instrument**

Event:	12-Month
Participant:	Child

**Respondent:** Parent/Caregiver

**Domain:** Biospecimen

Type of Document: Instrument

Allowable Mode: In Person

Allowable Method: CAPI

**Recruitment Groups:** EH, PB, HI

Version: 1.0

Release: MDES 3.0

Public reporting burden for this collection of information is estimated to average 15 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 Child Blood Instrument**

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# **Biospecimen Child Blood Instrument**

## (TIME\_STAMP\_1) PROGRAMMER INSTRUCTION:

• INSERT DATE/TIME STAMP.

**BL0100/(BLOOD\_INTRO).** I would like to collect a sample of {CHILD'S NAME/ the child}'s blood. Before I do so, I will explain this collection and ask you some questions.

#### DATA COLLECTOR INSTRUCTIONS:

- EXPLAIN THE CHILD BLOOD COLLECTION PROTOCOL TO THE PARENT OR CAREGIVER.
- IF THE PARENT OR CAREGIVER REFUSED THE COLLECTION, SELECT REFUSED. OTHERWISE, SELECT CONTINUE.

CONTINUE	1
REFUSED	-1

#### PROGRAMMER INSTRUCTIONS:

- PRELOAD PARTICIPANT ID (P\_ID) FOR CHILD AND RESPONDENT ID (R\_P\_ID) FOR RESPONDENT (MOTHER, FATHER, OTHER).
- PRELOAD CHILD'S FIRST NAME (BABY\_FNAME) AND DISPLAY NAME IN "CHILD'S NAME" THROUGHOUT DOCUMENT.
- USE "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT IF CHILD'S NAME IS REFUSED OR DON'T KNOW.
- PRELOAD CHILD SEX.
  - **o** IF **CHILD\_SEX** = 1, DISPLAY "his" AND "he" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.
  - IF CHILD\_SEX = 2, DISPLAY "her" AND "she" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.

## **DATA COLLECTOR COMPLETED QUESTION:**

**BL0100A/(RESP\_REL).** WHAT IS THE RELATIONSHIP OF THE PARENT OR CAREGIVER TO CHILD?

MOTHER	1
FATHER	2
OTHER	-5

- IF BLOOD INTRO = 1 AND RESP REL = 1 OR 2, GO TO HEMOPHILIA.
- IF BLOOD\_INTRO = -1 AND RESP\_REL = 1 OR 2, GO TO REFUSAL\_REASON.
- OTHERWISE, IF RESP REL = -5, GO TO RESP REL OTH.

BL0100B/(RESP_REL_OTH).	ı
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<b>SPECIFY</b>	•	

#### PROGRAMMER INSTRUCTIONS:

- LIMIT TEXT TO 255 CHARACTERS.
- IF BLOOD\_INTRO = 1, GO TO HEMOPHILIA.
- OTHERWISE, GO TO REFUSAL REASON.

**BL0100C/(REFUSAL\_REASON).** I am sorry that you have chosen not to participate in this collection. Can you tell me why?

#### DATA COLLECTOR INSTRUCTION:

• ENTER REASON FOR REFUSAL.

	OTHER	(BL2000)
	REFUSEDDON'T KNOW	
BL010	00D/(REFUSAL_REASON_OTH).	
	SPECIFY	(BL2000)

#### PROGRAMMER INSTRUCTION:

• LIMIT TEXT TO 255 CHARACTERS.

**BL0200/(HEMOPHILIA).** Has {CHILD'S NAME/the child} been diagnosed with hemophilia or any bleeding disorder?

#### DATA COLLECTOR INSTRUCTION:

RESPONSE DETERMINES ELIGIBILITY OF CHILD FOR BLOOD DRAW.

YES	1	(BL1600)
NO	2	
REFUSED	-1	(BL1900)
DON'T KNOW	-2	(BL1900)

**BL0300/(BLOOD\_THINNER).** Has {CHILD'S NAME/the child} taken any blood thinning medication, such as Coumadin or Warfarin?

#### **DATA COLLECTOR INSTRUCTION:**

 RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

YES	1	(BL1600)
NO	2	
REFUSED	-1	(BL1900)
DON'T KNOW	-2	(BL1900)

**BL0400/(CHEMO).** Has {CHILD'S NAME/the child} had cancer chemotherapy within the past 4 weeks?

#### DATA COLLECTOR INSTRUCTION:

 RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW

YES	1	(BL1600)
NO	2	
REFUSED	1	(BL1900)
DON'T KNOW:	2	(BL1900)

**BL0500/(BLOOD\_DRAW).** In the past, have there been any problems with taking blood from {CHILD'S NAME/the child}?

YES	1
NO	2 (LAST_EAT_
TIME/LAST_EAT_TIME_UNIT/LAST_	_EAT_DATE)
REFUSED	
TIME/LAST_EAT_TIME_UNIT/LAST_	_EAT_DATE)
DON'T KNOW	-2 (LAST_EAT_
TIME/LAST_EAT_TIME_UNIT/LAST_	_EAT_DATE)

**BL0600/(BLOOD\_DRAW\_PROB)**. What problems did {he/she} have with taking blood in the past?

#### DATA COLLECTOR INSTRUCTIONS:

- SELECT ALL THAT APPLY.
- PROBE: Any others?

FAINTING	1
HEMATOMA	
UNCOOPERATIVE/FIGETING/UNCONTROLLABLE	
CRYING	3
BRUISING	4
OTHER	
REFUSED	1
DON'T KNOW	

- IF BLOOD\_DRAW\_PROB = ANY COMBINATION OF 1 THROUGH 4, GO TO LAST EAT TIME/LAST EAT TIME UNIT/LAST EAT DATE
- IF **BLOOD\_DRAW\_PROB** = ANY COMBINATION OF 1 THROUGH 4, AND -5, GO TO **BLOOD DRAW OTH**.
- IF BLOOD DRAW PROB = -5, GO TO BLOOD DRAW OTH.
- IF **BLOOD\_DRAW\_PROB** = -1 OR -2, DO NOT ALLOW ANY OTHER RESPONSES AND GO TO **LAST\_EAT\_TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE**.
- BLOOD DRAW PROB CAN ONLY = -1 OR -2; NOT BOTH.

#### BL0600A/(BLOOD\_DRAW\_OTH).

#### **DATA COLLECTOR INSTRUCTION:**

• IF THERE WERE ANY PROBLEMS WITH A PAST BLOOD DRAW THAT ARE NOT LISTED IN THE PREVIOUS QUESTION, RECORD THE PROBLEM BELOW.

#### PROGRAMMER INSTRUCTION:

LIMIT TEXT TO 255 CHARACTERS.

**BL0700/(LAST\_EAT\_TIME/LAST\_EAT\_TIME\_UNIT/LAST\_EAT\_DATE).** When was the last time {CHILD'S NAME/the child} had anything to eat or drink other than water?

#### **DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE LAST TIME CHILD ATE OR DRANK ANYTHING OTHER THAN WATER.
- RECORD THE TIME AS HH:MM, 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 LAST TIME CHILD ATE OR DRANK WAS AT 2:05 PM, RECORD "02:05" AND CHOOSE "PM".
- RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

BL0700A/(LAST\_EAT\_TIME). LAST TIME ATE OR DRANK – TIME

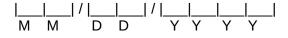
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REFUSED	-1
DON'T KNOW	-2

BL0700B/(LAST EAT TIME UNIT). LAST TIME ATE OR DRANK - AM/PM

AM	1
PM	2

BL0700C/(LAST EAT DATE). LAST TIME ATE OR DRANK - DATE



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 HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
- HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.</li>
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
- FORMAT DATE AS YYYYMMDD.

**BL1200/(VITAMIN).** Has {CHILD'S NAME/the child} taken a dietary supplement such as vitamins or minerals in the last 8 hours?

YES	1
NO	2
REFUSED	-1
DON'T KNOW	-2

**BL1500/(BLOOD\_COMPLETE).** Thank you for answering my questions. I am now going to prepare to draw blood.

CONTINUE	1	(TIME_STAMP_2)
REFUSED	-1	(BL2000)

**BL1600.** Because {CHILD'S NAME/the child} {has been diagnosed with a bleeding disorder/uses blood thinners/had cancer chemotherapy}, we will not be able to draw {his/her} blood for this study. **(TIME\_STAMP\_5)** 

#### PROGRAMMER INSTRUCTIONS:

- DISPLAY "has been diagnosed with a bleeding disorder" IF HEMOPHILIA=1.
- DISPLAY "uses blood thinners" IF **BLOOD THINNER**=1.
- DISPLAY "had cancer chemotherapy" IF CHEMO=1.

**BL1900.** Because you do not know or declined to answer questions about {CHILD'S NAME/the child's} {hemophilia/use of blood thinners/chemotherapy status}, we will not be able to draw {his/her} blood for this study. **(TIME\_STAMP\_5)** 

## PROGRAMMER INSTRUCTIONS:

- DISPLAY "hemophilia" IF **HEMOPHILIA** = -1 OR -2.
- DISPLAY "use of blood thinners" IF **BLOOD\_THINNER** = -1 OR -2.
- DISPLAY "chemotherapy status" IF **CHEMO** = -1 OR -2.

BL2000. That's fine. Thank you for your time. (TIME STAMP 5)

#### **BLOOD COLLECTION**

## (TIME\_STAMP\_2) PROGRAMMER INSTRUCTION:

INSERT DATE/TIME STAMP.

BL2100/(BLOOD INST). BLOOD DRAW INSTRUCTIONS

#### **DATA COLLECTOR INSTRUCTIONS:**

- CONFIRM THAT BLOOD TUBES ARE LABELED AND NOT EXPIRED PRIOR TO COLLECTION OF SPECIMEN.
- BE SURE TO EMPLOY UNIVERSAL PRECAUTIONS TO PREVENT EXPOSURE TO INFECTIOUS DISEASES AT ALL TIMES WHEN HANDLING BIOLOGICAL SPECIMENS.BE SURE TO EXPLAIN EACH PART OF PROCEDURE BEING PERFORMED DURING BLOOD COLLECTION.
- STOP DRAWING BLOOD IF BRUISING OCCURS.
- COLLECTION TUBES SHOULD BE DRAWN IN THE FOLLOWING ORDER:
  - **o** 3mL Lavender Top AA# # # # # # LV20
  - **o** 3mL Red top AA# # # # # # RD20
  - **o** 3mL Red top AA# # # # # # RD21
  - **o** 3mL Lavender top AA# # # # # # LV21

BL2100A/(COLLECTION\_LOCATION). COLLECTION LOCATION

#### DATA COLLECTOR INSTRUCTION:

RECORD WHERE BLOOD COLLECTION OCCURRED.

HOME	1
(CBLOOD_COLL_DATE)	
CLINIC	2
(CBLOOD_COLL_DATE)	
OTHER LOCATION	-5

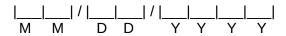
BL2100B/(COLLECTION LOCATION OTH).

SPECIFY		

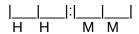
#### PROGRAMMER INSTRUCTION:

LIMIT TEXT TO 255 CHARACTERS.

BL2150/(CBLOOD\_COLL\_DATE). DATE CHILD BLOOD SPECIMEN COLLECTED



BL2150A/(CBLOOD COLL TIME). TIME CHILD BLOOD SPECIMEN COLLECTED



BL2150B/(CBLOOD\_COLL\_TIME\_UNIT). TIME CHILD BLOOD SPECIMEN COLLECTED – AM/PM

AM	1
PM	2

#### DATA COLLECTOR INSTRUCTION:

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

#### 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 HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
- HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.</li>
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
- FORMAT DATE AS YYYYMMDD.

**BL2200.** Thank you for {CHILD'S NAME/the child}'s blood sample.

## **DATA COLLECTOR INSTRUCTION:**

• CHECK IF CLOTTING HAS OCCURRED AND APPLY BAND-AID OVER GAUZE.

#### BL2400/(TUBE TYPE). ASSIGN TUBE TYPE

#### PROGRAMMER INSTRUCTIONS:

- LOOP THROUGH TUBE\_TYPE, SPECIMEN\_ID, TUBE\_STATUS, TUBE\_COMMENTS (IFAPPLICABLE) AND TUBE\_COMMENTS\_OTH (IF APPLICABLE) SEQUENTIALLY FOR EACH OF THE FOUR (4) BLOOD TUBES. THEN GO TO COLLECTION STATUS.
- DISPLAY CORRECT TUBE TYPE FOR EACH LOOP:
  - o IF FIRST CYCLE OF THE LOOP, THEN SET TUBE\_TYPE = 1 AND DISPLAY "3mL Lavender top (LV20)."
  - o IF SECOND CYCLE OF THE LOOP, THEN SET TUBE\_TYPE = 2 AND DISPLAY "3mL Red top (RD20)."
  - o IF THIRD CYCLE OF THE LOOP, THEN SET TUBE\_TYPE = 3 AND DISPLAY "3mL Red top (RD21)."
  - o IF FOURTH CYCLE OF THE LOOP, THEN SET TUBE\_TYPE = 4 AND DISPLAY "3mL Lavender top (LV21)."

#### BL2500/(SPECIMEN ID). SPECIMEN ID FOR {TUBE TYPE}

#### **DATA COLLECTOR INSTRUCTIONS:**

- SCAN {TUBE\_TYPE} BARCODE.
- IF THE BARCODE SCANNER IS NOT WORKING, MANUALLY ENTER THE INFORMATION.
- FORMAT SHOULD BE AA # # # # # # AA # #

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#### PROGRAMMER INSTRUCTIONS:

- DISPLAY CORRECT TUBE\_TYPE DESCRIPTION IN BRACKETS AND FORMAT FOR SPECIMEN ID FOR EACH LOOP:
  - **o** IF **TUBE\_TYPE** = 1, DISPLAY "3mL Lavender top, (LV20)" AND FORMAT AA# # # # # # + LV20.
  - o IF TUBE\_TYPE = 2, DISPLAY "3mL Red top (RD20)," AND FORMAT AA# # # # # # RD20.
  - o IF TUBE\_TYPE = 3, DISPLAY "3mL Red top (RD21)," AND FORMAT
  - **o** AA# # # # # # # RD21.
  - o IF TUBE\_TYPE = 4, DISPLAY "3mL Lavender top (LV21)," AND FORMAT AA# # # # # # LV21.

## BL2600/(TUBE\_STATUS). {TUBE\_TYPE} BLOOD TUBE COLLECTION STATUS

FULL DRAW	1
SHORT DRAW	2
NO DRAW	3

#### **DATA COLLECTOR INSTRUCTIONS:**

- ENTER STATUS OF {TUBE\_TYPE} BLOOD TUBE.
- SELECT "FULL DRAW" TO INDICATE THAT THE BLOOD TUBE WAS FILLED TO AT LEAST 3/4 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 3/4 OF THE DESIRED CAPACITY.
- SELECT "NO DRAW" TO INDICATE THAT THE BLOOD TUBE WAS NOT COLLECTED.

- DISPLAY CORRECT TUBE TYPE FOR LOOP:
  - o IF FIRST CYCLE OF THE LOOP, THEN TUBE\_TYPE = 1, DISPLAY "3mL Lavender top (LV20)".
  - o IF SECOND CYCLE OF THE LOOP, THEN TUBE\_TYPE = 2, DISPLAY "3mL Red top (RD20)".
  - o IF THIRD CYCLE OF THE LOOP, THEN TUBE\_TYPE = 3, DISPLAY "3mL Red top (RD21)".
  - **o** IF FOURTH CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 4, DISPLAY "3mL Lavender top (LV21)".
  - o IF TUBE\_STATUS = 2 OR 3, GO TO TUBE\_COMMENTS.
  - o OTHERWISE, IF TUBE STATUS = 1 AND
    - TUBE\_TYPE = 1, 2, OR 3, GO TO TUBE\_TYPE AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
    - o TUBE TYPE = 4, GO TO OVERALL COMMENTS.

**BL2700/(TUBE\_COMMENTS).** REASON {**TUBE\_TYPE**} BLOOD TUBE NOT COLLECTED OR DRAW WAS SHORT.

#### DATA COLLECTOR INSTRUCTION:

• ENTER REASONS {TUBE\_TYPE} WAS NOT COLLECTED OR DRAW WAS SHORT. SELECT ALL THAT APPLY

EQUIPMENT FAILURE	1
FAINTING	2
LIGHT-HEADEDNESS	3
HEMATOMA	4
BRUISING	5
VEIN COLLAPSED DURING PROCEDURE	_
NO SUITABLE VEIN	7
UNCOOPERATIVE/FIDGETING/UNCOTROLLABLE	
CRYING	8
PARENT/CAREGIVER REFUSED	9
OTHER	5

- DISPLAY CORRECT TUBE TYPE AS REFERENCE FOR LOOP:
  - o IF FIRST CYCLE OF THE LOOP, THEN TUBE\_TYPE = 1, DISPLAY "3mL Lavender top (LV20)".
  - o IF SECOND CYCLE OF THE LOOP, THEN TUBE\_TYPE = 2, DISPLAY "3mL Red top (RD20)".
  - o IF THIRD CYCLE OF THE LOOP, THEN TUBE\_TYPE = 3, DISPLAY "3mL Red top (RD21)".
  - **o** IF FOURTH CYCLE OF THE LOOP, THEN **TUBE\_TYPE** = 4, DISPLAY "3mL Lavender top (LV21)".
- IF **TUBE TYPE** = 1, 2, OR 3 AND
  - 0 TUBE\_COMMENTS = ANY COMBINATION OF 1 THROUGH 8, GO TO TUBE TYPE AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
  - 0 TUBE\_COMMENTS = -5 OR ANY COMBINATION OF 1 THROUGH 8 AND -5, GO TO TUBE COMMENTS OTH.
  - 0 TUBE\_COMMENTS = -1 OR -2, DO NOT ALLOW ANY OTHER RESPONSES, GO TO TUBE TYPE AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
- IF **TUBE\_TYPE** = 4 AND
  - o TUBE\_COMMENTS = ANY COMBINATION OF 1 THROUGH 8, GO TO COLLECTION STATUS.
  - o TUBE\_COMMENTS = -5 OR ANY COMBINATION OF 1 THROUGH 8 AND -5, GO TO TUBE COMMENTS OTH.
  - TUBE\_COMMENTS = -1 OR -2, DO NOT ALLOW ANY OTHER RESPONSES AND GO TO COLLECTION\_STATUS.

BL2700A/(TUBE_C	MMENTS_OTH)
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SPECIFY	
-	

#### PROGRAMMER INSTRUCTIONS:

- LIMIT TEXT TO 255 CHARACTERS.
- IF **TUBE\_TYPE** = 1, 2, OR 3 GO TO **TUBE\_TYPE** AND LOOP THROUGH REMAINING BLOOD SPECIMENS.
- IF TUBE TYPE = 4, GO TO COLLECTION STATUS.

## BL2800/(COLLECTION STATUS). BLOOD TUBE COLLECTION OVERALL STATUS

COLLECTED	1
PARTIALLY COLLECTED	2
NOT COLLECTED	3

#### PROGRAMMER INSTRUCTIONS:

- COLLECTION\_STATUS = 1 IF EACH TUBE\_TYPE HAS A TUBE\_STATUS = 1.
- COLLECTION\_STATUS = 2 IF AT LEAST 1 BUT LESS THAN 4 TUBES HAVE A TUBE STATUS = 1 OR THAT ALL TUBES HAVE A TUBE STATUS = 2.
- COLLECTION\_STATUS = 3 IF EACH TUBE TYPE HAS A TUBE\_STATUS = 3
- IF COLLECTION STATUS = 1 OR 2, GO TO TIME\_STAMP\_3.
- OTHERWISE, GO TO OVERALL\_COMMENTS.

BL2900/(OVERALL\_COMMENTS). BLOOD COLLECTION OVERALL COMMENTS

#### DATA COLLECTOR INSTRUCTION:

ENTER MAIN REASON BLOOD WAS NOT COLLECTED.

SAFETY EXCLUSION	1
(BLOOD_DRAW_COMMENT)	
PHYSICAL LIMITATION	2
(BLOOD_DRAW_COMMENT)	
CAREGIVER ILL/EMERGENCY	3
(BLOOD_DRAW_COMMENT)	
QUANTITY NOT SUFFICIENT4	1
(BLOOD_DRAW_COMMENT)	
CHILD ILL/EMERGENCY	5
(BLOOD_DRAW_COMMENT)	
NO TIME	3
(BLOOD_DRAW_COMMENT)	
PARENT/CAREGIVER REFUSED	7
(BLOOD_DRAW_COMMENT)	
OTHER	5

## BL2900A/(OVERALL\_COMMENTS\_OTH)

SPECIFY (BLOOD\_DRAW\_COMMENT)

#### PROGRAMMER INSTRUCTION:

LIMIT TEXT TO 255 CHARACTERS.

#### **BLOOD CENTRIFUGATION**

## (TIME STAMP 3) PROGRAMMER INSTRUCTION:

• INSERT DATE/TIME STAMP.

BL3000/(CENTRIFUGE_LOCATION). CENTRIFUGATION LOCATION								
•		COLLECTOR IFUGED.	INSTRUCTIONS:	RECORD	WHERE	BLOOD	WILL	BE
	SPSC		N LOCATION		2 <b>(</b>			
BL300	0A/(CEN	NTRIFUGE_LOC	ATION_OTH).					
SPECI	IFY		<u></u>					
		R INSTRUCTIO EXT TO 255 CH						
BL310	0/(EQUI	<b>P_ID).</b> EQUIPME	ENT ID FOR CENTR	RIFUGE				
DATA •		CTOR INSTRUC EQUIPMENT ID	TION: FOR CENTRIFUGI	Ξ.				
BL312	:5/(CENT	TRIFUGE_STAR	T_DATE_TIME). DA	TE AND TIM	ИЕ CENTR	IFUGATIC	N BEG	ΔN

#### **DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE TIME THE BLOOD TUBES WERE PLACED IN THE CENTRIFUGE.
- RECORD THE TIME AS HH:MM, BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO CHOOSE "AM" OR "PM." FOR EXAMPLE, IF THE BLOOD TUBES WERE PLACED IN THE CENTRIFUGE AT 2:05 PM, RECORD "02:05" AND CHOOSE "PM."
- RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

BL3125A/(CENTRIFUGE\_START\_TIME). CENTRIFUGE START - TIME

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BL3125B/(CENTRIFUGE START TIME UNIT). CENTRIFUGE START - AM/PM

AM	- 1
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## BL3125C/(CENTRIFUGE\_START\_DATE). CENTRIFUGE START - DATE

#### 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 HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.
- HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
- 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.
- FORMAT DATE AS YYYYMMDD.

## BL3130/(CENTRIFUGE\_END\_DATE\_TIME).TIME CENTRIFUGATION ENDED

#### **DATA COLLECTOR INSTRUCTIONS:**

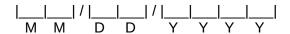
- RECORD THE TIME CENTRIFUGATION WAS COMPLETED.
- RECORD THE TIME AS HH:MM, BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY AND TO MARK THE BOX TO CHOOSE "AM" OR "PM." FOR EXAMPLE, IF CENTRIFUGATION WAS COMPLETED AT 2:05 PM, RECORD "02:05" AND CHOOSE "PM."
- RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

**BL3130A/(CENTRIFUGE\_END\_TIME).** CENTRIFUGE END – TIME

BL3130B/(CENTRIFUGE\_END\_TIME\_UNIT). CENTRIFUGE END – AM/PM

AM	1
PM	2

BL3130C/(CENTRIFUGE END DATE). CENTRIFUGE END - DATE



- 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 HOUR OR MONTH IS NOT BETWEEN 01 AND 12.
- HARD EDIT: INCLUDE HARD EDIT IF MINUTES ARE NOT BETWEEN 00 AND 59.

- HARD EDIT: INCLUDE HARD EDIT IF DAY IS NOT BETWEEN 01 AND 31.
- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2011.</li>
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME OR LESS THAN CENTRIFUGE\_START\_TIME AND/OR CENTRIFUGE START DATE.
- FORMAT DATE AS YYYYMMDD.

BL3140/(CENTRIFUGE TEMP MEASURE). TEMPERATURE OF CENTRIFUGE

#### **DATA COLLECTOR INSTRUCTIONS:**

- IF ABLE TO MEASURE CENTRIFUGE TEMPERATURE, SELECT "TEMPERATURE."
- IF NOT ABLE TO MEASURE CENTRIFUGE TEMPERATURE, THEN SELECT "NOT ABLE TO MEASURE" AND THE REASON THE TEMPERATURE COULD NOT BE RECORDED.

#### PROGRAMMER INSTRUCTION:

LIMIT TEXT TO 255 CHARACTERS.

BL3150/(CENTRIFUGE\_TEMP/CENT\_TEMP\_POSNEG). TEMPERATURE OF CENTRIFUGE

#### DATA COLLECTOR INSTRUCTIONS:

- RECORD THE TEMPERATURE READING ON THE DIGITAL THERMOMETER ATTACHED TO THE CENTRIFUGE AT THE TIME THAT THE BLOOD TUBES ARE REMOVED AFTER CENTRIFUGATION.
- ENTER TEMPERATURE IN DEGREES CELSIUS.

**BL3150A**/(**CENTRIFUGE\_TEMP**). RECORD THE TEMPERATURE TO THE FIRST DECIMAL POINT.

\_\_\_\_\_. \_\_\_°C

#### PROGRAMMER INSTRUCTIONS:

- SOFT EDIT: DISPLAY SOFT EDIT IF TEMPERATURE IS < 15.0 °C OR > 25.0 °C
- SOFT EDIT: DISPLAY SOFT EDIT IF NO VALUE ENTERED IN THE FIRST DECIMAL POINT.

**BL3150B/(CENT\_TEMP\_POSNEG**). RECORD IF THE TEMPERATURE IS A POSITIVE OR NEGATIVE VALUE.

<ul> <li>DATA COLLECTOR INSTRUCTIONS:</li> <li>IF TEMPERATURE IS ZERO OR ABOVE, RECORD "POSITIVE."</li> <li>IF TEMPERATURE IS BELOW ZERO, RECORD "NEGATIVE."</li> </ul>
POSITIVE
BL3160/(BLOOD_HEMOLYZE). DID BLOOD HEMOLYZE?
<ul> <li>DATA COLLECTOR INSTRUCTION:</li> <li>RECORD WHETHER HEMOLYSIS OCCURRED IN ONE OR MORE OF THE BLOOD TUBES.</li> </ul>
YES, ALL TUBES HEMOLYZED
BL3170/(V1_TUBE_HEMOLYZE) INDICATE WHICH TUBE(S) HEMOLYZED.
<ul><li>DATA COLLECTOR INSTRUCTION:</li><li>SELECT ALL THAT APPLY:</li></ul>
(TUBE_TYPE)= 1, 3mL Lavender top (LV20)
PROGRAMMER INSTRUCTION:  • DISPLAY THE FOLLOWING RESPONSE CATEGORIES:
(TUBE_TYPE)= 1, 3mL Lavender top (LV20)
BL3180/(CENTRIFUGE_COMMENT). CENTRIFUGE OTHER COMMENTS
DATA COLLECTOR INSTRUCTION:  ● ENTER CENTRIFUGE COMMENTS:  NO COMMENTS
BL3185/(CENTRIFUGE_COMMENT_OTH).
<ul><li>• ENTER ANY CENTRIFUGE COMMENT.</li></ul>
SPECIFY

## PROGRAMMER INSTRUCTION:

• LIMIT FREE TEXT TO 255 CHARACTERS.

## PREPARATION FOR BLOOD TUBE TRANSPORT

## (TIME\_STAMP\_4) PROGRAMMER INSTRUCTION:

• INSERT DATE/TIME STAMP.

BL3200/(COLD\_TEMP\_MEASURE). TEMPERATURE OF REFRIGERATED CHAMBER

## **DATA COLLECTOR INSTRUCTIONS:**

- PREPARE THE TUBES FOR TRANSPORT IN EITHER THE REFRIGERATED CLAMSHELL OR IN THE AMBIENT TUBE HOLDER, DEPENDING ON THE TUBE TYPE AND LOCATION OF CENTRIFUGATION.
- PLACE A LOWER THRESHOLD (0.0°C) MONITOR INSIDE THE REFRIGERATED CLAMSHELL AND INSIDE THE AMBIENT TUBE HOLDER (IF APPLICABLE).
- ACTIVATE AN UPPER THRESHOLD (20.0°C) MONITOR AND AFFIX IT TO THE OUTSIDE OF THE REFRIGERATED CLAMSHELL.
- 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."
- IF THERE ARE NOT ANY TUBES THAT REQUIRE REFRIGERATED TRANSPORT TEMPERATURES, THEN SELECT "NOT APPLICABLE."

TEMPERATURE		.1 (COLD_TEMP/
COLD_TEMP_POSNEG)		•
NOT ABLE TO MEASURE - TH	HERMOMETER BROKEN	.2
(COLD_THRESHOLD_LOW)		
NOT ABLE TO MEASURE - TH	HERMOMETER NOT	
AVAILABLE		.3
(COLD_THRESHOLD_LOW)		
NOT ABLE TO MEASURE - O	ГНЕR	5
NOT APPLICABLE		7
(COLD_THRESHOLD_LOW)		
BL3200A/(COLD_TEMP_MEASURE_	OTH).	
SPECIFY	_(COLD_THRESHOLD_LOW	)

#### PROGRAMMER INSTRUCTION:

LIMIT TEXT TO 255 CHARACTERS.

BL3300/(COLD\_TEMP/COLD\_TEMP\_POSNEG). RECORD TEMPERATURE OF REFRIGERATED CHAMBER

## DATA COLLECTOR INSTRUCTION:

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

BL3300A/(COLD_TEMP). ENTER TEMPERATURE IN DEGREES CELSIUS.
<b>3300B/COLD_TEMP_POSNEG</b> ). RECORD IF THE TEMPERATURE IS A POSITIVE OR NEGATIVE VALUE
<ul> <li>DATA COLLECTOR INSTRUCTIONS:</li> <li>IF TEMPERATURE IS ZERO OR ABOVE, RECORD "POSITIVE."</li> <li>IF TEMPERATURE IS BELOW ZERO, RECORD "NEGATIVE."</li> </ul>
POSITIVE
<b>BL3400/(COLD_THRESHOLD_LOW).</b> STATUS OF REFRIGERATED CHAMBER LOW THRESHOLD MONITOR
<ul> <li>DATA COLLECTOR INSTRUCTION:</li> <li>RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.</li> </ul>
YES, IN CHAMBER
<b>BL3500/(COLD_THRESHOLD_HIGH).</b> STATUS OF REFRIGERATED CHAMBER HIGH THRESHOLD MONITOR
DATA COLLECTOR INSTRUCTION:  • RECORD STATUS OF THE HIGH THRESHOLD MONITOR IN THE REFRIGERATED COMPARTMENT OF THE COOLER.
YES, IN CHAMBER
<ul> <li>PROGRAMMER INSTRUCTIONS:</li> <li>IF 12-MONTH VISIT, GO TO TIME_STAMP_5.</li> <li>OTHERWISE, GO TO AMBIENT_THRESHOLD_LOW.</li> </ul>

**BL3600/(AMBIENT\_THRESHOLD\_LOW).** STATUS OF AMBIENT LOW THRESHOLD MONITOR

<ul> <li>DATA COLLECTOR INSTRUCTION:</li> <li>RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE AMBIENT COMPARTMENT OF THE COOLER.</li> </ul>
YES, IN CHAMBER
BL3650/(TRANSPORT_COMMENT). TRANSPORT COMMENT
NO COMMENTS
BL3660/(TRANSPORT_COMMENT_OTH).
DATA COLLECTOR INSTRUCTION:
PROGRAMMER INSTRUCTION:  • LIMIT TEXT TO 255 CHARACTERS.
BL3700/(BLOOD_DRAW_COMMENT). ADDITIONAL BLOOD DRAW COMMENT
<ul><li>DATA COLLECTOR INSTRUCTION:</li><li>ENTER ANY ADDITIONAL BLOOD COLLECTION COMMENTS:</li></ul>
NO COMMENTS
BL3750/(BLOOD_DRAW_COMMENT_OTH).
SPECIFY

## (TIME\_STAMP\_5) PROGRAMMER INSTRUCTION:

• INSERT DATE/TIME STAMP.