Child Blood Instrument

Event Category:	Time-Based
Event:	12M, 36M, 60M
Administration:	N/A
Instrument Target:	Child
Instrument Respondent:	Primary Caregiver
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:	13 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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Child Blood Instrument

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Child Blood 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 CHARACTERS 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 CHARACTER	• DISPLAY AS MM/DD/YYYY • STORE AS YYYY-MM-DD • HARD EDITS: MM MUST EQUAL 01 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	NUMERIC	• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59

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.**

BIOSPECIMEN CHILD BLOOD INSTRUMENT

(TIME_STAMP_BCB_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP. • PRELOAD PARTICIPANT ID **(P_ID)** FOR CHILD AND RESPONDENT ID **(R_P_ID)** FOR ADULT CAREGIVER. • PRELOAD CHILD'S FIRST NAME AND DISPLAY NAME IN **C_FNAME** THROUGHOUT INSTRUMENT • OTHERWISE, IF **C_FNAME** = -1 OR -2, DISPLAY "the child" IN APPROPRIATE FIELDS THROUGHOUT THE INSTRUMENT. • IF **CHILD_SEX** IN PARTICIPANT VERIFICATION QUESTIONNAIRE = 1, DISPLAY "his", "he", OR "himself" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT. • IF **CHILD_SEX** IN PARTICIPANT VERIFICATION QUESTIONNAIRE = 2, DISPLAY "her", "she", OR "herself" IN APPROPRIATE FIELDS THROUGHOUT INSTRUMENT.

BCB01000/(BLOOD_INTRO). I would like to collect a sample of {C_FNAME/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 ADULT CAREGIVER. • IF THE ADULT CAREGIVER REFUSED THE COLLECTION, SELECT REFUSED. OTHERWISE, SELECT CONTINUE.

Label	Code	Go To
CONTINUE	**1**	**HEMOPHILIA**
REFUSED	**-1**	

SOURCE
National Children's Study, Vanguard Phase (12M Child Blood)

BCB04000/(REFUSAL_REASON). I am sorry that you have chosen not to participate in this collection. Can you tell me why?

DATA COLLECTOR INSTRUCTIONS
• ENTER REASON FOR REFUSAL.

Label	Code	Go To
CHILD HAS FEVER/OTHER ILLNESS	**1**	**BCB21000**
OTHER	**-5**	
REFUSED	**-1**	**BCB21000**
DON'T KNOW	**-2**	**BCB21000**

SOURCE
National Children's Study, Legacy Phase (Modified) (6M Child)

BCB05000/(REFUSAL_REASON_OTH).
SPECIFY: _____

SOURCE
National Children's Study, Legacy Phase (Modified) (6M Child)

PROGRAMMER INSTRUCTIONS
• GO TO **BCB21000.**

BCB06000/(HEMOPHILIA). Has {C_FNAME/the child} been diagnosed with hemophilia or any bleeding disorder?

DATA COLLECTOR INSTRUCTIONS
• RESPONSE DETERMINES ELIGIBILITY OF CHILD FOR BLOOD DRAW.

Label	Code	Go To
YES	1	BCB19000
NO	2	
REFUSED	-1	BCB20000
DON'T KNOW	-2	BCB20000

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

BCB08000/(CHEMO). Has {C_FNAME/the child} had cancer chemotherapy within the past 4 weeks?

DATA COLLECTOR INSTRUCTIONS
• RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

Label	Code	Go To
YES	1	BCB19000
NO	2	
REFUSED	-1	BCB20000
DON'T KNOW	-2	BCB20000

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

BCB09000/(LAST_BLOOD_DR AW). Has {C_FNAME/the child} had blood drawn in the last 24 hours?

DATA COLLECTOR INSTRUCTIONS
• RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

Label	Code	Go To
YES	1	BCB19000
NO	2	
REFUSED	-1	BCB20000
DON'T KNOW	-2	BCB20000

SOURCE
New

BCB10000/(BLOOD_DRAW). Has {C_FNAME/the child} had any problems with a blood draw in the past?

Label	Code	Go To
YES	1	
NO	2	BCB13000
REFUSED	-1	BCB13000
DON'T KNOW	-2	BCB13000

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

BCB11000/(BLOOD_DRAW_PROB). What problems did {he/she} have with a blood draw in the past?

DATA COLLECTOR INSTRUCTIONS
• SELECT ALL THAT APPLY. • PROBE: Any others?

Label	Code	Go To
FAINTING	1	
HEMATOMA	2	
UNCOOPERATIVE/FIDGETING/ UNCONTROLLABLE CRYING	3	
BRUISING	4	
OTHER	-5	
REFUSED	-1	
DON'T KNOW	-2	

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

PROGRAMMER INSTRUCTIONS
• IF **BLOOD_DRAW_PROB** = ANY COMBINATION OF 1 THROUGH 4, GO TO **BCB13000.** • IF **BLOOD_DRAW_PROB**= -5 OR ANY COMBINATION OF 1 THROUGH 4 AND -5, GO TO **BLOOD_DRAW_PROB_OTH**. • IF **BLOOD_DRAW_PROB**= -1 OR -2, DO NOT ALLOW SELECTION OF ADDITIONAL RESPONSES AND GO TO **BCB13000**.

BCB12000/(BLOOD_DRAW_PROB_OTH). SPECIFY: _____

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

SOURCE
National Children's Study, Vanguard Phase **Modified (Adult Blood)** **National Children's Study, Legacy Phase**

BCB13000. When was the last time {C_FNAME/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 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.

SOURCE
National Children's Study, Vanguard Phase **Modified (Adult Blood)** **National Children's Study, Legacy Phase**

(LAST_EAT_TIME) LAST TIME ATE OR DRANK –TIME

|___|___|:|___|___|
H H M M

Label	Code	Go To
REFUSED	**-1**	
DON'T KNOW	**-2**	

(LAST_EAT_TIME_UNIT) LAST TIME ATE OR DRANK – UNIT

Label	Code	Go To
AM	**1**	

Label	Code	Go To
PM	**2**	
REFUSED	**-1**	
DON'T KNOW	**-2**	

(LAST_EAT_MM) LAST TIME ATE OR DRANK – DATE: MONTH

|___|___|
M M

Label	Code	Go To
REFUSED	**-1**	
DON'T KNOW	**-2**	

(LAST_EAT_DD) LAST TIME ATE OR DRANK – DATE: DAY

|___|___|
D D

Label	Code	Go To
REFUSED	**-1**	
DON'T KNOW	**-2**	

(LAST_EAT_YYYY) LAST TIME ATE OR DRANK – DATE: YEAR

|___|___|___|___|
Y Y Y Y

Label	Code	Go To
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 YEAR ≠ CURRENT YEAR. • HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.

BCB17000/(VITAMIN). Has {C_FNAME/the child} taken a dietary supplement such as vitamins or minerals in the last 8 hours?

Label	Code	Go To
YES	**1**	
NO	**2**	
REFUSED	**-1**	
DON'T KNOW	**-2**	

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

BCB18000/(BLOOD_COMPLETE). Thank you for answering my questions. I am now going to prepare to draw {C_FNAME/the child}'s blood.

Label	Code	Go To
CONTINUE	1	TIME_STAMP_BCB_ET
REFUSED	-1	REFUSAL_REASON

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

BCB19000. Because {C_FNAME/the child} {has been diagnosed with a bleeding disorder/had cancer chemotherapy/had blood drawn in the last 24 hours}, we will not be able to draw {his/her} blood for this study.

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

PROGRAMMER INSTRUCTIONS
• DISPLAY "has been diagnosed with a bleeding disorder" IF **HEMOPHILIA**=1. • DISPLAY "had cancer chemotherapy" IF **CHEMO**=1. • DISPLAY "had blood drawn in the last 24 hours" IF **LAST_BLOOD_DRAW**=1. • GO TO **BCB21000**.

BCB20000. Because you do not know or declined to answer questions about {C_FNAME/the child}'s {hemophilia/chemotherapy status/blood drawn in last 24 hours}, we will not be able to draw {his/her} blood for this study.

SOURCE
National Children's Study, Vanguard Phase Modified (Adult Blood) National Children's Study, Legacy Phase

PROGRAMMER INSTRUCTIONS
• DISPLAY "hemophilia" IF **HEMOPHILIA** = -1 OR-2. • DISPLAY "chemotherapy status" IF **CHEMO** = -1OR -2. • DISPLAY "blood drawn in last 24 hours" IF **LAST_BLOOD_DRAW**= -1 OR -2.

BCB21000. That's fine. Thank you for your time.

SOURCE
National Children's Study, Vanguard Phase **Modified (Adult Blood)** **National Children's Study, Legacy Phase**

PROGRAMMER INSTRUCTIONS
• GO TO **BLOOD_DRAW_COMMENT**.

(TIME_STAMP_BCB_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

BLOOD COLLECTION

(TIME_STAMP_BC_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

BC01000/(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**:**
    - IF 12 MONTH VISIT
        - 3mL Lavender top, prescreened (LP20)
        - 3mL Red top (RD20)
        - 3mL Red top (RD21)
        - 3mL Lavender top (LV21)
    - IF 36 MONTH VISIT
        - 3mL Lavender top, prescreened (LP20)
        - 3.5mL Gold top SST (SS20)
        - 5mL Red top (RD22)
        - 4mL Lavender top (LV22)
        - 2.5mL Clear top PAXgene™ (PX20)
    - IF 60 MONTH VISIT
        - 3mL Lavender top, prescreened (LP20)
        - 6mL Royal blue top, serum (RS20)
        - 5mL Gold top SST (SS22)
        - 4mL Lavender top (LV22)

BC02000/(COLLECTION_LOCATION). COLLECTION LOCATION

DATA COLLECTOR INSTRUCTIONS

- RECORD WHERE BLOOD COLLECTION OCCURRED.

Label	Code	Go To
HOME	**1**	**BC04000**
CLINIC	**2**	**BC04000**
HOSPITAL	**3**	**BC04000**
OTHER	**-5**	

BC03000/(COLLECTION_LOCATION_OTH).
SPECIFY: _____

BC04000. DATE CHILD BLOOD SPECIMEN COLLECTED

DATA COLLECTOR INSTRUCTIONS
• RECORD THE DATE AS TWO-DIGIT MONTH, TWO-DIGIT DAY, AND FOUR-DIGIT YEAR.

(CBLOOD_COLL_MM) |___|___|
M M

(CBLOOD_COLL_DD) |___|___|
D D

(CBLOOD_COLL_YYYY) |___|___|___|___|
Y Y Y Y

BC05000. TIME CHILD BLOOD SPECIMEN COLLECTED

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 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'.

(CBLOOD_COLL_TIME) |___|___|:|___|___|
H H H H

(CBLOOD_COLL_TIME_UNIT) TIME CHILD BLOOD SPECIMEN COLLECTED – AM/PM

Label	Code	Go To
AM	**1**	
PM	**2**	

BC07000. Thank you for {C_FNAME/the child}'s blood sample.

DATA COLLECTOR INSTRUCTIONS
• CHECK IF CLOTTING HAS OCCURRED AND APPLY BANDAGE OVER GAUZE.

BC08000/(TUBE_STATUS). {**TUBE_TYPE**} BLOOD TUBE COLLECTION STATUS

Label	Code	Go To
FULL DRAW	**1**	
SHORT DRAW	**2**	**TUBE_COMMENTS**
NO DRAW	**3**	**TUBE_COMMENTS**

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.

DATA COLLECTOR INSTRUCTIONS

- 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.

PROGRAMMER INSTRUCTIONS

- LOOP THROUGH **TUBE_STATUS, SPECIMEN_ID, TUBE_COMMENTS** (IF APPLICABLE) AND **TUBE_COMMENTS_OTH** (IF APPLICABLE) SEQUENTIALLY FOR EACH OF THE FOUR (4) OR FIVE (5) BLOOD TUBES.
- DISPLAY CORRECT **TUBE_TYPE** FOR LOOP:
- IF **EVENT_TYPE** = 27 (12 MONTH VISIT):
  - IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 1, DISPLAY ”3mL Lavender top, prescreened (LP20)”.
  - IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 2, DISPLAY ”3mL Red top (RD20)”.
  - IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 3, DISPLAY ”3mL Red top (RD21)”.
  - IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 4, DISPLAY ”3mL Lavender top (LV21)”.
- IF **EVENT_TYPE** = 37 (36 MONTH VISIT):
  - IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE_TYPE**= 1, DISPLAY ”3mL Lavender top, prescreened (LP20)”.
  - IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 5, DISPLAY ”3.5mL Gold top SST (SS20)”.
  - IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 6, DISPLAY ”5mL Red top (RD22)”.
  - IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 7, DISPLAY ”4mL Lavender top (LV22)”.
  - IF FIFTH CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 8, DISPLAY ”2.5mL Clear top PAXgene™ (PX20)”.
- IF **EVENT_TYPE**= XX (60 MONTH VISIT):
  - IF FIRST CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 1 AND DISPLAY “3mL Lavender top, prescreened (LP20).”
  - IF SECOND CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 9 AND DISPLAY “6mL Royal blue top, serum (RS20).”
  - IF THIRD CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 10 AND DISPLAY “5mL Gold top SST (SS22).”
  - IF FOURTH CYCLE OF THE LOOP, THEN SET **TUBE_TYPE** = 7 AND DISPLAY “4mL Lavender top (LV22).”

BC09000/(SPECIMEN_ID). ENTER SPECIMEN ID FOR {**TUBE_TYPE**}

|___|___|___|___|___|___|___|___|___| -|___|___|___|___|

DATA COLLECTOR INSTRUCTIONS

- SCAN {**TUBE_TYPE**} BARCODE.
- IF THE BARCODE SCANNER IS NOT WORKING, RECORD THE INFORMATION.

PROGRAMMER INSTRUCTIONS
• DISPLAY CORRECT **TUBE_TYPE** AND REFERENCE FORMAT FOR **SPECIMEN_ID** FOR EACH LOOP. o IF **TUBE_TYPE** = 1, DISPLAY ”3mL Lavender top, prescreened (LP20)” AND FORMAT AS A A # # # # # # # # - LP20. o IF **TUBE_TYPE** = 2, DISPLAY ”3mL Red top (RD20)” AND FORMAT AS A A # # # # # # # # - RD20. o IF **TUBE_TYPE** = 3, DISPLAY ”3mL Red top (RD21)” AND FORMAT AS A A # # # # # # # # - RD21. o IF **TUBE_TYPE** = 4, DISPLAY ”3mL Lavender top (LV21)” AND FORMAT AS A A # # # # # # # # - LV21. o IF **TUBE_TYPE** = 5, DISPLAY ”3.5mL Gold top SST (SS20)” AND FORMAT AS A A # # # # # # # # - SS20. o IF **TUBE_TYPE** = 6, DISPLAY ”5mL Red top (RD22)” AND FORMAT AS A A # # # # # # # # - RD22. o IF **TUBE_TYPE** = 7, DISPLAY ”4mL Lavender top (LV22)” AND FORMAT AS A A # # # # # # # # - LV22. o IF **TUBE_TYPE** = 8, DISPLAY ”2.5mL Clear top PAXgene™ (PX20)” AND FORMAT AS A A # # # # # # # # - PX20. o IF **TUBE_TYPE** = 9, DISPLAY “6mL Royal blue top, serum (RS20)” AND FORMAT AS A A # # # # # # # # - RS20. o IF **TUBE_TYPE** = 10, DISPLAY “5mL Gold top SST (SS22)" AND FORMAT AS A A # # # # # # # # - SS22.

BC11000/(TUBE_COMMENTS). REASON {**TUBE_TYPE**} BLOOD TUBE NOT COLLECTED OR DRAW WAS SHORT.

DATA COLLECTOR INSTRUCTIONS
• ENTER REASONS {**TUBE_TYPE**} WAS NOT COLLECTED OR DRAW WAS SHORT. • SELECT ALL THAT APPLY.

Label	Code	Go To
EQUIPMENT FAILURE	**1**	
FAINTING	**2**	
LIGHT-HEADEDNESS	**3**	
HEMATOMA	**4**	
BRUISING	**5**	
VEIN COLLAPSED DURING PROCEDURE	**6**	
NO SUITABLE VEIN	**7**	
UNCOOPERATIVE/FIDGETING/ UNCONTROLLABLE CRYING	**8**	
ADULT CAREGIVER REFUSED	**9**	
OTHER	**-5**	

PROGRAMMER INSTRUCTIONS
• DISPLAY CORRECT **TUBE_TYPE** o IF **TUBE_TYPE** = 1, DISPLAY ”3mL Lavender top, prescreened (LP20)” o IF **TUBE_TYPE** = 2, DISPLAY ”3mL Red top (RD20)”

PROGRAMMER INSTRUCTIONS
o IF **TUBE_TYPE** = 3, DISPLAY ”3mL Red top (RD21)” o IF **TUBE_TYPE** = 4, DISPLAY ”3mL Lavender top (LV21)” o IF **TUBE_TYPE** = 5, DISPLAY ”3.5mL Gold top SST (SS20)” o IF **TUBE_TYPE** = 6, DISPLAY ”5mL Red top (RD22)” o IF **TUBE_TYPE** = 7, DISPLAY ”4mL Lavender top (LV22)” o IF **TUBE_TYPE** = 8, DISPLAY ”2.5mL Clear top PAXgene™ (PX20)” o IF **TUBE_TYPE** = 9, DISPLAY “6mL Royal blue top, serum (RS20)” o IF **TUBE_TYPE** = 10, DISPLAY “5mL Gold top SST (SS22)" • IF THIS IS NOT THE LAST LOOP, AND o **TUBE_COMMENTS** = ANY COMBINATION OF 1 THROUGH 9, GO TO **TUBE_STATUS** AND LOOP THROUGH REMAINING BLOOD SPECIMENS. o **TUBE_COMMENTS** = -5 OR ANY COMBINATION OF 1 THROUGH 9 AND -5, GO TO **TUBE_COMMENTS_OTH**. • IF THIS IS THE LAST LOOP, AND o **TUBE_COMMENTS** = ANY COMBINATION OF 1 THROUGH 9, GO TO **COLLECTION_STATUS.** o **TUBE_COMMENTS** = -5 OR ANY COMBINATION OF 1 THROUGH 9 AND -5, GO TO **TUBE_COMMENTS_OTH.**

BC12000/(TUBE_COMMENTS_OTH). SPECIFY: _____

PROGRAMMER INSTRUCTIONS
• IF THIS IS NOT THE LAST LOOP, GO TO **TUBE_STATUS** AND LOOP THROUGH REMAINING BLOOD SPECIMENS. • OTHERWISE, GO TO **COLLECTION_STATUS.**

BC13000/(COLLECTION_STATUS). BLOOD TUBE COLLECTION OVERALL STATUS

Label	Code	Go To
COLLECTED	**1**	**TIME_STAMP_BC_ET**
PARTIALLY COLLECTED	**2**	**TIME_STAMP_BC_ET**
NOT COLLECTED	**3**	

PROGRAMMER INSTRUCTIONS
• **COLLECTION_STATUS** = 1 IF EACH **TUBE_TYPE** HAS A **TUBE_STATUS** = 1. • **COLLECTION_STATUS** = 2 o IF **EVENT_TYPE** = 27 OR XX (60-MONTH VISIT), AND IF AT LEAST 1 BUT LESS THAN 4 TUBES HAVE A **TUBE_STATUS** = 1 OR ALL TUBES HAVE A **TUBE_STATUS** = 2. o IF **EVENT_TYPE** = 37 AND IF AT LEAST 1 BUT LESS THAN 5 TUBES HAVE A **TUBE_STATUS** = 1 OR ALL TUBES HAVE A **TUBE_STATUS** = 2. • **COLLECTION_STATUS** = 3 IF EACH **TUBE_TYPE** HAS A **TUBE_STATUS** =3.

BC14000/(OVERALL_COMMENTS). BLOOD COLLECTION OVERALL COMMENTS

DATA COLLECTOR INSTRUCTIONS
• ENTER MAIN REASON BLOOD WAS NOT COLLECTED.

Label	Code	Go To
SAFETY EXCLUSION	**1**	**BLOOD_DRAW_COMMENT**
PHYSICAL LIMITATION	**2**	**BLOOD_DRAW_COMMENT**
CAREGIVER ILL/EMERGENCY	**3**	**BLOOD_DRAW_COMMENT**
QUANTITY NOT SUFFICIENT	**4**	**BLOOD_DRAW_COMMENT**
CHILD ILL/EMERGENCY	**5**	**BLOOD_DRAW_COMMENT**
NO TIME	**6**	**BLOOD_DRAW_COMMENT**
ADULT CAREGIVER REFUSED	**7**	**BLOOD_DRAW_COMMENT**
OTHER	**-5**	

BC15000/(OVERALL_COMMENTS_OTH). SPECIFY: _____

PROGRAMMER INSTRUCTIONS
• GO TO **BLOOD_DRAW_COMMENT**.

(TIME_STAMP_BC_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

BLOOD CENTRIFUGATION

(TIME_STAMP_BCF_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

BCF01000/(CENTRIFUGE_LOCATION). CENTRIFUGATION LOCATION

DATA COLLECTOR INSTRUCTIONS
• RECORD WHERE BLOOD WILL BE CENTRIFUGED.

Label	Code	Go To
DEFAULT COLLECTION LOCATION	**1**	**EQUIP_ID**
SPSC	**2**	**TIME_STAMP_BCF_ET**
OTHER	**-5**	

BCF02000/(CENTRIFUGE_LOCATION_OTH). SPECIFY: _____

BCF03000/(EQUIP_ID). EQUIPMENT ID FOR CENTRIFUGE

_____

DATA COLLECTOR INSTRUCTIONS
• ENTER EQUIPMENT ID FOR CENTRIFUGE.

BCF04000. DATE AND TIME CENTRIFUGATION BEGAN

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 YEAR ≠ CURRENT YEAR. • HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME ARE GREATER THAN CURRENT DATE AND TIME.

(CENTRIFUGE_START_TIME) CENTRIFUGE START – TIME

|___|___|:|___|___|
H H M M

(CENTRIFUGE_START_TIME_UNIT) CENTRIFUGE START – AM/PM

Label	Code	Go To
AM	**1**	
PM	**2**	

(CENTRIFUGE_START_MM) CENTRIFUGE START – DATE: MONTH

|___|___|
M M

(CENTRIFUGE_START_DD) CENTRIFUGE START – DATE: DAY

|___|___|
D D

(CENTRIFUGE_START_YYYY) CENTRIFUGE START – DATE: YEAR

|___|___|___|___|
Y Y Y Y

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.

BCF08000. TIME CENTRIFUGATION ENDED

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 YEAR ≠ CURRENT YEAR. • HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME ARE GREATER THAN CURRENT DATE AND TIME OR LESS THAN CENTRIFUGE_START_TIME AND/OR CENTRIFUGE_START_DATE.

(CENTRIFUGE_END_TIME) CENTRIFUGE END – TIME

|___|___|:|___|___|
H H M M

(CENTRIFUGE_END_TIME_UNIT) CENTRIFUGE END – AM/PM

Label	Code	Go To
AM	**1**	
PM	**2**	

(CENTRIFUGE_END_MM) CENTRIFUGE END – DATE: MONTH

|___|___|
M M

PROGRAMMER INSTRUCTIONS
• HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME ARE GREATER THAN CURRENT DATE AND TIME OR LESS THAN **CENTRIFUGE_START_TIME** AND/OR **CENTRIFUGE_START_DATE**.

(CENTRIFUGE_END_DD) CENTRIFUGE END – DATE: DAY

|___|___|
D D

(CENTRIFUGE_END_YYYY) CENTRIFUGE END – DATE: YEAR

|___|___|___|___|
Y Y Y Y

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.

BCF12000/(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. • OTHERWISE, SELECT OTHER AND SPECIFY

Label	Code	Go To
TEMPERATURE	**1**	**BCF14000**
NOT ABLE TO MEASURE-THERMOMETER BROKEN	**2**	**BLOOD_HEMOLYZE**
NOT ABLE TO MEASURE-THERMOMETER NOT AVAILABLE	**3**	**BLOOD_HEMOLYZE**
NOT ABLE OT MEASURE-OTHER	**-5**	

BCF13000/(CENTRIFUGE_TEMP_MEASURE_OTH). SPECIFY: _____

PROGRAMMER INSTRUCTIONS
• GO TO **BLOOD_HEMOLYZE**.

BCF14000. 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

DATA COLLECTOR INSTRUCTIONS
REMOVED AFTER CENTRIFUGATION. • ENTER TEMPERATURE IN DEGREES CELSIUS.

BCF15000/(CENTRIFUGE_TEMP). RECORD THE TEMPERATURE TO THE FIRST DECIMAL POINT.

|___|___| . |___| °C

PROGRAMMER INSTRUCTIONS
• SOFT EDIT: DISPLAY SOFT EDIT IF TEMPERATURE IS < 15.0ºC OR > 25.0ºC • SOFT EDIT: DISPLAY SOFT EDIT IF NO VALUE ENTERED IN THE FIRST DECIMAL POINT.

BCF16000/(CENT_TEMP_POSNEG). RECORD WHETHER 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**	

BCF17000/(BLOOD_HEMOLYZE). DID BLOOD HEMOLYZE?

DATA COLLECTOR INSTRUCTIONS
• RECORD WHETHER HEMOLYSIS OCCURRED IN ONE OR MORE OF THE BLOOD TUBES.

Label	Code	Go To
YES, ALL TUBES HEMOLYZED	**1**	
YES, AT LEAST ONE TUBE HEMOLYZED AND AT LEAST ONE TUBE DID NOT HEMOLYZE	**2**	
NO, NONE OF THE TUBES HEMOLYZED	**3**	**CENTRIFUGE_COMMENT**

BCF18000/(V1_TUBE_HEMOLYZE). INDICATE WHICH TUBE(S) HEMOLYZED.

DATA COLLECTOR INSTRUCTIONS
• SELECT ALL THAT APPLY

Label	Code	Go To
3mL Red top (RD20)	**1**	
3mL Red top (RD21)	**2**	
3.5mL SST (SS20)	**3**	

Label	Code	Go To
5mL Red top (RD22)	**4**	
5mL SST (SS22)	**5**	

PROGRAMMER INSTRUCTIONS
• DISPLAY THE FOLLOWING RESPONSE CATEGORIES: • IF **EVENT_TYPE** = 27 (12 MONTH VISIT): 3mL Red top (RD20)..... .. 1 3mL Red top (RD21)..... 2 • IF **EVENT_TYPE** = 37 (36 MONTH VISIT): 3.5mL SST (SS20)..... 3 5mL Red top (RD22)..... .. 4 • IF **EVENT_TYPE** = XX (60 MONTH VISIT):5mL Red top (RD22)..... .. 4 5mL SST (SS22)..... 5

BCF19000/(CENTRIFUGE_COMMENT). CENTRIFUGE OTHER COMMENTS

DATA COLLECTOR INSTRUCTIONS
• ENTER CENTRIFUGE COMMENTS.

Label	Code	Go To
NO COMMENTS	**1**	**TIME_STAMP_BCF_ET**
COMMENT	**2**	

BCF20000/(CENTRIFUGE_COMMENT_OTH). SPECIFY: _____

DATA COLLECTOR INSTRUCTIONS
• ENTER ANY CENTRIFUGE COMMENT.

(TIME_STAMP_BCF_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

PREPARATION FOR BLOOD TUBE TRANSPORT

(TIME_STAMP_PFB_ST).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.

PFB01000/(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) AND ACTIVATE. • 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” 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**	**PFB03000**
NOT ABLE TO MEASURE – THERMOMETER BROKEN	**2**	**COLD_THRESHOLD_LOW**
NOT ABLE TO MEASURE – THERMOMETER NOT AVAILABLE	**3**	**COLD_THRESHOLD_LOW**
NOT ABLE TO MEASURE – OTHER	**-5**	
NOT APPLICABLE	**-7**	**COLD_THRESHOLD_LOW**

PFB02000/(COLD_TEMP_MEASURE_OTH). SPECIFY: _____

PROGRAMMER INSTRUCTIONS
• GO TO **COLD_THRESHOLD_LOW**.

PFB03000. RECORD TEMPERATUREOF REFRIGERATED CHAMBER

DATA COLLECTOR INSTRUCTIONS
• RECORD THE TEMPERATURE OF THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.

PFB04000/(COLD_TEMP). ENTER TEMPERATURE IN DEGREES CELSIUS.

|___|___|. |___| °C

PFB05000/(COLD_TEMP_POSNEG). RECORD WHETHER 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 TEMPERATURE IS ≥10.0ºC OR ≤ 0.0ºC. • SOFT EDIT: DISPLAY SOFT EDIT IF NO VALUE ENTERED IN THE FIELD FOLLOWING THE DECIMAL POINT.

PFB06000/(COLD_THRESHOLD_LOW). STATUS OF REFRIGERATED CHAMBER LOW THRESHOLD MONITOR

DATA COLLECTOR INSTRUCTIONS
• RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.

Label	Code	Go To
YES, IN CHAMBER	**1**	
NO, NOT REQUIRED	**2**	
NO, NOT AVAILABLE	**3**	

PFB07000/(COLD_THRESHOLD_HIGH). STATUS OF REFRIGERATED CHAMBER UPPER THRESHOLD MONITOR

DATA COLLECTOR INSTRUCTIONS
• RECORD STATUS OF THE UPPER THRESHOLD MONITOR IN THE REFRIGERATED COMPARTMENT OF THE COOLER.

Label	Code	Go To
YES, IN CHAMBER	**1**	
NO, NOT REQUIRED	**2**	
NO, NOT AVAILABLE	**3**	

PROGRAMMER INSTRUCTIONS
• IF **EVENT_TYPE** = 27 (12-MONTH VISIT), GO TO **TRANSPORT_COMMENT**. • OTHERWISE, GO TO **AMBIENT_THRESHOLD_LOW**.

PFB08000/(AMBIENT_THRESHOLD_LOW). STATUS OF AMBIENT LOW THRESHOLD MONITOR

DATA COLLECTOR INSTRUCTIONS
• RECORD STATUS OF THE LOW THRESHOLD MONITOR IN THE AMBIENT COMPARTMENT OF THE COOLER.

Label	Code	Go To
YES, IN CHAMBER	**1**	
NO, NOT REQUIRED	**2**	
NO, NOT AVAILABLE	**3**	

PFB09000/(TRANSPORT_COMMENT). TRANSPORT COMMENT

Label	Code	Go To
NO COMMENTS	**1**	**BLOOD_DRAW_COMMENT**
COMMENT	**2**	

PFB10000/(TRANSPORT_COMMENT_OTH).

_____

DATA COLLECTOR INSTRUCTIONS
• ENTER ANY TRANSPORT COMMENT.

PFB11000/(BLOOD_DRAW_COMMENT). ADDITIONAL BLOOD DRAW COMMENT

DATA COLLECTOR INSTRUCTIONS
• ENTER ANY ADDITIONAL BLOOD COLLECTION COMMENTS.

Label	Code	Go To
NO COMMENTS	**1**	**TIME_STAMP_PFB_ET**
COMMENT	**2**	

PFB12000/(BLOOD_DRAW_COMMENT_OTH).
SPECIFY: _____

(TIME_STAMP_PFB_ET).

PROGRAMMER INSTRUCTIONS
• INSERT DATE/TIME STAMP.