



Biospecimen Adult Blood Instrument

Event:	Pregnancy Visit 1, Pregnancy Visit 2, Birth
Participant:	Pregnant or Non-Pregnant Woman
Domain:	Biospecimen
Type of Document:	Data Collection Instrument
Recruitment Groups:	EH, PB, HI, PBS
Version:	2.0
Release:	MDES 3.3

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.

This page intentionally left blank.

Biospecimen Adult Blood Instrument

TABLE OF CONTENTS

BIOSPECIMEN BLOOD COLLECTION.....	1
BLOOD COLLECTION.....	6
BLOOD CENTRIFUGATION.....	15
PREPARATION FOR BLOOD TUBE TRANSPORT.....	19

Biospecimen Adult Blood Instrument

BIOSPECIMEN BLOOD COLLECTION

(TIME_STAMP_1) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

BL0100/(BLOOD_INTRO). I will now collect a blood sample. I will need to ask you some questions before I collect your blood sample.

DATA COLLECTOR INSTRUCTIONS:

- IF THE PARTICIPANT REFUSES THIS COLLECTION, SELECT REFUSED. OTHERWISE SELECT CONTINUE.

CONTINUE..... 1
REFUSED..... -1 **(BL2000)**

BL0200/(HEMOPHILIA). Do you have hemophilia or any bleeding disorder?

DATA COLLECTOR INSTRUCTIONS:

- RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

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

BL0300/(BLOOD_THINNER). Do you take any blood thinning medication, such as Coumadin or warfarin?

DATA COLLECTOR INSTRUCTIONS:

- RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

YES..... 1 **(BL1700)**
NO..... 2
REFUSED..... -1 **(BL1900)**
DON'T KNOW..... -2 **(BL1900)**

BL0400/(CHEMO). Have you had cancer chemotherapy within the past 4 weeks?

DATA COLLECTOR INSTRUCTIONS:

- RESPONSE DETERMINES ELIGIBILITY OF STUDY PARTICIPANT FOR BLOOD DRAW.

YES..... 1 **(BL1800)**
NO..... 2
REFUSED..... -1 **(BL1900)**
DON'T KNOW..... -2 **(BL1900)**

BL0500/(BLOOD_DRAW). Have you had any problems with taking blood in the past?

YES..... 1
NO..... 2 **(LAST_DATE_TIME_EAT)**
REFUSED..... -1 **(LAST_DATE_TIME_EAT)**
DON'T KNOW..... -2 **(LAST_DATE_TIME_EAT)**

BL0600/(BLOOD_DRAW_PROB). What problems did you have with taking blood in the past?

SELECT ALL THAT APPLY.

FAINTING..... 1
LIGHT-HEADEDNESS 2
HEMATOMA..... 3
BRUISING..... 4
OTHER.....-5
REFUSED.....-1
DON'T KNOW.....-2

PROGRAMMER INSTRUCTIONS:

- IF **BLOOD_DRAW_PROB**= ANY COMBINATION OF 1 THROUGH 4, GO TO **LAST_DATE_TIME_EAT**.
- 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_DATE_TIME_EAT**.

BL0650/(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.

SPECIFY: _____
 REFUSED..... -1
 DON'T KNOW..... -2

PROGRAMMER INSTRUCTION:

- LIMIT FREE TEXT TO 255 CHARACTERS.

BL0700/(LAST_DATE_TIME_EAT). When was the last time you had anything to eat or drink other than water?

DATA COLLECTOR INSTRUCTIONS:

- RECORD THE LAST TIME PARTICIPANT 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 PARTICIPANT ATE OR DRANK WAS AT 2:05PM RECORD "02:05" AND CHOOSE "PM".
- RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.

BL0700A/(LAST_TIME_EAT). LAST TIME ATE OR DRANK – TIME

|_|_|_|:|_|_|_|
 H H M M

BL0700B/(LAST_TIME_EAT_UNIT). LAST TIME ATE OR DRANK – AM/PM

AM..... 1
 PM..... 2

BL0700C/(LAST_DATE_EAT). LAST TIME ATE OR DRANK – DATE

|_|_|_|/|_|_|_|/|_|_|_|_|_|_|_|
 M M D D Y Y Y Y

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

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH, OR DAY ARE NOT 2 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.
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
- FORMAT DATE AS YYYYMMDD

BL0800/(COFFEE_TEA). Have you had coffee or tea with sweetener or milk in the last 8 hours?

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

BL0900/(ALCOHOL). Have you had alcohol such as beer, wine, or liquor in the last 8 hours?

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

BL1000/(COUGH_COLD). Have you chewed gum, or used breath mints, lozenges, cough drops, or other cough or cold remedies in the last 8 hours?

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

BL1100/(LAXATIVE). Have you used antacid, laxatives, or anti-diarrheal medication in the last 8 hours?

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

BL1200/(VITAMIN). Have you taken a dietary supplement such as vitamins or minerals in the last 8 hours?

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

BL1300/(DIABETES). Are you diabetic? This includes gestational diabetes?

YES.....1
NO..... 2 **(BLOOD_COMPLETE)**
REFUSED.....-1 **(BLOOD_COMPLETE)**
DON'T KNOW.....-2 **(BLOOD_COMPLETE)**

BL1400/(INSULIN). Have you taken any insulin 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 your blood

CONTINUE.....1 **(TIME_STAMP_2)**
REFUSED.....-1 **(BL2000)**

BL1600. Because you have hemophilia, we will not be able to draw your blood for this study. **(TIME_STAMP_5)**

BL1700. Because you are taking a blood thinning medication, we will not be able to draw your blood at this time. **(TIME_STAMP_5)**

BL1800. Because you've had chemotherapy recently, we will not be able to draw your blood at this time. **(TIME_STAMP_5)**

BL1900. Because you do not know or declined to answer questions about your {hemophilia/chemotherapy status/use of blood thinners} we will not be able to draw your blood. **(TIME_STAMP_5)**

PROGRAMMER INSTRUCTION:

- **DISPLAY APPROPRIATE RESPONSE IN BRACKETS:**
 - o IF **HEMOPHILIA**=-1 OR -2, DISPLAY "hemophilia".
 - o IF **CHEMO** =-1 OR -2, DISPLAY "chemotherapy status".
 - o IF **BLOOD_THINNER** =-1 OR -2, DISPLAY "use of blood thinners".

(BL2000). That's fine. Thank you. **(TIME_STAMP_5)**

(TIME_STAMP_2) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

BLOOD COLLECTION

BL2100/(BLOOD_INST). BLOOD DRAW INSTRUCTIONS

DATA COLLECTOR INSTRUCTIONS:

- CONFIRM THAT BLOOD TUBES ARE LABELED AND NOT EXPIRED PRIOR TO COLLECTION OF SAMPLE.
- BE SURE TO EMPLOY UNIVERSAL PRECAUTIONS TO PREVENT EXPOSURE TO INFECTIOUS DISEASES AT ALL TIMES WHEN HANDLING BIOLOGICAL SPECIMENS.
- WEAR PPE INCLUDING A LAB COAT AND GLOVES UNTIL SAMPLES ARE SEALED IN TRANSPORT BAG.
- BE SURE TO EXPLAIN EACH PART OF PROCEDURE BEING PERFORMED DURING BLOOD COLLECTION.
- ONCE IN AN AREA WITH ADEQUATE LIGHT AND A FLAT, CLEAN SURFACE FREE OF FOOD, CLUTTER AND DISTRACTIONS, BEGIN SET UP.
- IDEALLY THE PREP AREA SHOULD BE NEAR A PLACE WHERE THE PARTICIPANT CAN SIT WITH HER/HIS ARM STRETCHED OUT ON A FLAT SURFACE.
- DRAPE A CHUX PAD OVER SURFACES WHERE THE PARTICIPANT WILL PUT HER/HIS ARM.
- STOP DRAWING BLOOD IF BRUISING OCCURS. CONTINUE AFTER THREE MINUTES ONLY WITH VERBAL PERMISSION OF PARTICIPANT.
- COLLECTION TUBES SHOULD BE DRAWN IN THE FOLLOWING ORDER:
TUBE_TYPE.
- ONCE COLLECTION IS COMPLETE, REMOVE THE NEEDLE AND APPLY GAUZE.

PROGRAMMER INSTRUCTIONS:

- IF PRE-PREGNANCY VISIT NOT SET TO COMPLETE AND PREGNANCY VISIT 1 NOT SET TO COMPLETE, DISPLAY THE FOLLOWING BLOOD TUBES:

(TUBE_TYPE)=1 8.5mL SST.....AA#####-SS10
(TUBE_TYPE)=2 10 mL Red top.....AA#####-RD10
(TUBE_TYPE)=3 5mL PPTAA#####-PP10
(TUBE_TYPE)=4 6mL LavenderAA#####-LV10
(TUBE_TYPE)=5 8.5mL P100.....AA#####-PN10
(TUBE_TYPE)=6 8.5mL ACDAA#####-AD10

- IF PRE-PREGNANCY VISIT SET TO COMPLETE, OR IF PREGNANCY VISIT 1 SET TO COMPLETE AND PREGNANCY VISIT 2 NOT SET TO COMPLETE, DISPLAY THE FOLLOWING BLOOD TUBES:

(TUBE_TYPE)=7 6mL Royal Blue Trace MetalAA#####-RB10
(TUBE_TYPE)=1 8.5mL SST.....AA#####-SS10
(TUBE_TYPE)=2 10 mL Red top.....AA#####-RD10
(TUBE_TYPE)=3 5mL PPTAA#####-PP10
(TUBE_TYPE)=4 6mL LavenderAA#####-LV10
(TUBE_TYPE)=8 2.5mL Paxgene.....AA#####-PX10

BL2200. Thank you for your blood sample. Please hold this gauze on your arm with mild pressure.

DATA COLLECTOR INSTRUCTIONS:

- CHECK IF CLOTTING HAS OCCURRED AND APPLY BAND-AID OVER GAUZE.
- IF NECESSARY, INSTRUCT PARTICIPANT TO RAISE HER ARM ABOVE HER HEAD FOR TWO MINUTES WITHOUT BENDING HER ELBOW TO PREVENT THE FORMATION OF A HEMATOMA.

BL2400/ (TUBE_TYPE). ASSIGN TUBE_TYPE

PROGRAMMER INSTRUCTION:

- LOOP THROUGH TUBE_TYPE, SPECIMEN_ID, TUBE_STATUS, TUBE_COMMENTS AND TUBE_COMMENTS_OTH (IF NEEDED) FOR ALL SIX (6) BLOOD TUBES
- DISPLAY CORRECT TUBE_TYPE FOR EACH LOOP:
 - o IF , (PRE-PREGNANCY VISIT NOT SET TO COMPLETE AND PREGNANCY VISIT 1 NOT SET TO COMPLETE)
 - AND IF FIRST CYCLE OF THE LOOP, THEN (TUBE_TYPE)=1 DISPLAY "8.5mL SST"
 - AND IF SECOND CYCLE OF THE LOOP, THEN (TUBE_TYPE)=2, DISPLAY "10mL Red top"

- o IF **TUBE_TYPE**=1, DISPLAY "8.5ML SST", AND FORMAT AA# # # # # # - SS10
- o IF **TUBE_TYPE**=2, DISPLAY "10mL Red top", AND FORMAT AA# # # # # # - RD10
- o IF **TUBE_TYPE**=3, DISPLAY "5ML PPT", AND FORMAT AA# # # # # # - PP10
- o IF **TUBE_TYPE**=4, DISPLAY "6ML LAVENDER", AND FORMAT AA# # # # # # - LV10
- o IF **TUBE_TYPE**=5, DISPLAY "8.5ML P100", AND FORMAT AA# # # # # # - PN10
- o IF **TUBE_TYPE**=6, DISPLAY "8.5ML ACD", AND FORMAT AA# # # # # # - AD10
- o IF **TUBE_TYPE**=7, DISPLAY "6ML ROYAL BLUE TRACE METAL", AND FORMAT AA# # # # # # - RB10
- o IF **TUBE_TYPE**=8, DISPLAY "2.5ML PAXGENE", AND FORMAT AA# # # # # # - PX10

BL2600/(TUBE_STATUS). BLOOD TUBE COLLECTION STATUS

DATA COLLECTOR INSTRUCTIONS:

- ENTER STATUS OF {**TUBE_TYPE**}.
- 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.

FULL DRAW.....	1	SHORT DRAW	2
NO DRAW.....	3		

PROGRAMMER INSTRUCTIONS:

- DISPLAY CORRECT **TUBE_TYPE** AS A REFERENCE FOR EACH LOOP:
 - o IF (PRE-PREGNANCY VISIT NOT SET TO COMPLETE AND PREGNANCY VISIT 1 NOT SET TO COMPLETE)
 - AND IF FIRST CYCLE OF THE LOOP, THEN (**TUBE_TYPE**)=1 DISPLAY "8.5mL SST"

- AND IF SECOND CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=2**,
DISPLAY "10mL Red top"
 - AND IF THIRD CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=3**
DISPLAY "5mL PPT"
 - AND IF FOURTH CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=4**
DISPLAY "6mL Lavender"
 - AND IF FIFTH CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=5**,
DISPLAY "8.5mL P100"
 - AND IF SIXTH CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=6**,
DISPLAY "8.5mL ACD"
- o IF PRE-PREGNANCY VISIT SET TO COMPLETE, OR IF PREGNANCY VISIT 1 SET TO COMPLETE AND PREGNANCY VISIT 2 NOT SET TO COMPLETE VISIT 1 OR PREGNANCY VISIT 2)
- AND IF FIRST CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=7**,
DISPLAY "6mL Royal Blue Trace Meta"
 - AND IF SECOND CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=1**,
DISPLAY "8.5mL SST"
 - AND IF THIRD CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=2**,
DISPLAY "10mL Red top"
 - AND IF FOURTH CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=3**,
DISPLAY "5mL PPT"
 - AND IF FIFTH CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=4** ,
DISPLAY "6mL Lavender"
 - AND IF SIXTH CYCLE OF THE LOOP, THEN **(TUBE_TYPE)=8**,
DISPLAY "2.5mL Paxgene"
- IF FIRST THROUGH FIFTH LOOP AND **TUBE_STATUS=1**, GO TO **TUBE_TYPE** TO LOOP THROUGH REMAINING BLOOD SPECIMENS.
 - IF SIXTH LOOP AND **TUBE_STATUS=1**, GO TO **COLLECTION_LOCATION**.
 - OTHERWISE, GO TO **TUBE_COMMENTS**.

BL2700/(TUBE_COMMENTS). REASON 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.....	6
NO SUITABLE VEIN	7
OTHER.....	-5
REFUSED.....	-1
DON'T KNOW.....	-2

PROGRAMMER INSTRUCTIONS:

- DISPLAY CORRECT **TUBE_TYPE** AS REFERENCE FOR LOOP:
 - IF , (PRE-PREGNANCY VISIT NOT SET TO COMPLETE AND PREGNANCY VISIT 1 NOT SET TO COMPLETE)

- AND IF FIRST CYCLE OF THE LOOP, THEN **TUBE_TYPE=1** DISPLAY "8.5mL SST"
- AND IF SECOND CYCLE OF THE LOOP, THEN **TUBE_TYPE=2**, DISPLAY "10mL Red top"
- AND IF THIRD CYCLE OF THE LOOP, THEN **TUBE_TYPE=3** DISPLAY "5mL PPT"
- AND IF FOURTH CYCLE OF THE LOOP, THEN **TUBE_TYPE=4** DISPLAY "6mL Lavender"
- AND IF FIFTH CYCLE OF THE LOOP, THEN **TUBE_TYPE=5**, DISPLAY "8.5mL P100"
- AND IF SIXTH CYCLE OF THE LOOP, THEN **TUBE_TYPE=6**, DISPLAY "8.5mL ACD"

IF PRE-PREGNANCY VISIT SET TO COMPLETE, OR IF PREGNANCY VISIT 1 SET TO COMPLETE AND PREGNANCY VISIT 2 NOT SET TO COMPLETE AND IF FIRST CYCLE OF THE LOOP, THEN **TUBE_TYPE=7**, DISPLAY "6mL Royal Blue Trace Meta"

- AND IF SECOND CYCLE OF THE LOOP, THEN **TUBE_TYPE=1**, DISPLAY "8.5mL SST"
- AND IF THIRD CYCLE OF THE LOOP, THEN **TUBE_TYPE=2**, DISPLAY "10mL Red top"

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 MONTH OR DAY ARE NOT 2 DIGITS (FILL THE SPACE WITH 0 AS NECESSARY)
- 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.
- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2011.
- HARD EDIT: INCLUDE HARD EDIT IF DATE IS GREATER THAN CURRENT DATE.
- FORMAT DATE AS YYYYMMDD

BL2850/(COLLECTION_STATUS). BLOOD TUBE COLLECTION OVERALL STATUS

COLLECTED.....1
 PARTIALLY COLLECTED.....2
 NOT COLLECTED.....3

PROGRAMMERS INSTRUCTIONS:

- THIS VALUE PROVIDES AN OVERALL STATUS OF BLOOD COLLECTION USING THE **TUBE_STATUS** (FULL DRAW=1, SHORT DRAW=2, NO DRAW=3) AND **TUBE_TYPE** (1, 2, 3, 4, 5, 6, 7 and 8, depending on the visit).
- “COLLECTED” INDICATES THAT ALL BLOOD TUBES ARE 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. THIS CHOICE SHOULD NOT BE SELECTED IF THERE ARE ANY PARTIALLY FILLED TUBES.
- “PARTIALLY COLLECTED” INDICATES THAT AT LEAST ONE, BUT NOT ALL OF THE BLOOD TUBES IS FILLED TO AT LEAST 3/4 OF THE DESIRED CAPACITY OR THAT ALL TUBES WERE FILLED TO LESS THAN 3/4 OF THE DESIRED CAPACITY.
- “NOT COLLECTED” INDICATES THAT NO BLOOD TUBES WERE COLLECTED.
- **COLLECTION_STATUS=1** IF EACH **TUBE_TYPE** HAS A **TUBE_STATUS=1**.
COLLECTION_STATUS=2 IF AT LEAST 1 BUT LESS THAN 6 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_COMMENT.

BL2900/(OVERALL_COMMENTS). BLOOD COLLECTION OVERALL COMMENTS

DATA COLLECTOR INSTRUCTION:

- ENTER REASON BLOOD WAS NOT COLLECTED.

SAFETY EXCLUSION.....	1	(BLOOD_DRAW_COM)
PHYSICAL LIMITATION.....	2	(BLOOD_DRAW_COM)
PARTICIPANT ILL/EMERGENCY.....	3	(BLOOD_DRAW_COM)
QUANTITY NOT SUFFICIENT.....	4	(BLOOD_DRAW_COM)
LANGUAGE ISSUE, SPANISH	5	(BLOOD_DRAW_COM)
LANGUAGE ISSUE, NON SPANISH	6	(BLOOD_DRAW_COM)
COGNITIVE DISABILITY.....	7	(BLOOD_DRAW_COM)
NO TIME.....	8	(BLOOD_DRAW_COM)
OTHER.....	-5	
REFUSED.....	-1	(BLOOD_DRAW_COM)
DON'T KNOW.....	-2	(BLOOD_DRAW_COM)

BL2950/(OVERALL_COMMENTS_OTH).

DATA COLLECTOR INSTRUCTION:

- IF THERE ARE ANY OTHER BLOOD COLLECTION COMMENTS NOT LISTED IN THE PREVIOUS QUESTION, ENTER THEM BELOW.

_____ (BLOOD_DRAW_COM)

PROGRAMMER INSTRUCTIONS:

- LIMIT FREE TEXT TO 255 CHARACTERS.

BLOOD CENTRIFUGATION

(TIME_STAMP_3) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

BL3000/(CENTRIFUGE_LOCATION). WILL BLOOD BE CENTRIFUGED AT COLLECTION LOCATION?

DATA COLLECTOR INSTRUCTION:

- RECORD WHETHER BLOOD WILL BE CENTRIFUGED AT COLLECTION LOCATION,

YES..... 1
NO..... 2 **(TIME_STAMP_4)**

BL3100/(EQUIP_ID). EQUIPMENT ID FOR CENTRIFUGE

DATA COLLECTOR INSTRUCTIONS:

- ENTER EQUIPMENT ID FOR CENTRIFUGE.

BL3125/(CENTRIFUGE_ST). TIME CENTRIFUGATION BEGAN

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 MARK THE BOX 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_TIME). TIME CENTRIFUGATION BEGAN – TIME

|_|_|:|_|_|
H H M M

BL3125B/(CENTRIFUGE_TIME_UNIT). TIME CENTRIFUGATION BEGAN – AM/PM

AM..... 1
PM..... 2

BL3125C/(CENTRIFUGE_DATE). TIME CENTRIFUGATION BEGAN – DATE

|_|_|/|_|_|/|_|_|_|_|
M M D D Y Y Y Y

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

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH, OR DAY ARE NOT 2 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.
- 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 2:05PM RECORD “02:05” AND CHOOSE “PM”.
- RECORD THE DATE AS TWO DIGIT MONTH, TWO DIGIT DAY, AND FOUR DIGIT YEAR.

BL3130A/(CENTRIFUGE_END_TIME). TIME CENTRIFUGATION ENDED – TIME

|_|_|:|_|_|
H H M M

BL3130B/(CENTRIFUGE_END_TIME_UNIT). TIME CENTRIFUGATION ENDED – AM/PM

AM..... 1
PM..... 2

BL3130C/(CENTRIFUGE_END_DATE). TIME CENTRIFUGATION ENDED – DATE

|_|_|/|_|_|/|_|_|_|_|
M M D D Y Y Y Y

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

PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF HOURS, MINUTES, MONTH, OR DAY ARE NOT 2 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.
- HARD EDIT: INCLUDE HARD EDIT IF DATE AND TIME IS GREATER THAN CURRENT DATE AND TIME.
- FORMAT DATE AS YYYYMMDD

BL3140/(CENTRIFUGE_TEMP_MEASURE). TEMPERATURE OF CENTRIFUGE

DATA COLLECTOR INSTRUCTION:

- IF ABLE TO MEASURE TEMPERATURE, THEN SELECT "TEMPERATURE". IF NOT ABLE TO MEASURE TEMPERATURE, THEN SELECT "NOT ABLE TO MEASURE".

TEMPERATURE..... 1
NOT ABLE TO MEASURE..... 2 **(BLOOD_HEMOLYZE)**

BL3150/(CENTRIFUGE_TEMP). 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.
- 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

BL3160/(BLOOD_HEMOLYZE). DID BLOOD HEMOLYZE?

DATA COLLECTOR INSTRUCTION:

- RECORD WHETHER HEMOLYSIS OCCURRED IN ONE OR MORE OF THE BLOOD TUBES,

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 **(TIME_STAMP_4)**

BL3170/(V1_TUBE_HEMOLYZE) INDICATE WHICH TUBE(S) HEMOLYZED

SELECT ALL THAT APPLY:

PROGRAMMER INSTRUCTIONS:

- IF VISIT IS PARTICIPANT'S FIRST VISIT (PRE-PREGNANCY OR PREGNANCY VISIT 1), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:

(TUBE_TYPE)=1, 8.5mL SST..... 1
(TUBE_TYPE)=2, 10 mL Red top..... 2
(TUBE_TYPE)=3, 5mL PPT..... 3
(TUBE_TYPE)=5, 8.5mL P100..... 4

- IF VISIT IS PARTICIPANT'S SECOND VISIT (PREGNANCY VISIT 1 OR PREGNANCY VISIT 2), DISPLAY THE FOLLOWING RESPONSE CATEGORIES:

(TUBE_TYPE)=1, 8.5mL SST..... 1
(TUBE_TYPE)=2, 10 mL Red top..... 2
(TUBE_TYPE)=3, 5mL PPT..... 3

BL3180/(CENTRIFUGE_COMMENT). CENTRIFUGE OTHER COMMENTS

DATA COLLECTOR INSTRUCTION:

- ENTER CENTRIFUGE COMMENTS:

NO COMMENTS..... 1 **(TIME_STAMP_4)**
COMMENT.....2

BL3185/(CENTRIFUGE_COMMENT_OTH).

DATA COLLECTOR INSTRUCTION:

- ENTER ANY OTHER CENTRIFUGE COMMENTS.

PROGRAMMER INSTRUCTION:

LIMIT FREE TEXT TO 255 CHARACTERS.

(TIME_STAMP_4) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP
PREPARATION FOR BLOOD TUBE TRANSPORT

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
NOT ABLE TO MEASURE..... 2 (COLD_THRESHOLD_LOW)
NOT APPLICABLE..... -7 (COLD_THRESHOLD_LOW)

BL3300/(COLD_TEMP). RECORD TEMPERATURE OF REFRIGERATED CHAMBER

DATA COLLECTOR INSTRUCTIONS:

- RECORD THE TEMPERATURE OF THE REFRIGERATED CHAMBER OF THE TRANSPORT COOLER.
- ENTER TEMPERATURE IN DEGREES CELSIUS.

|_|_|.|_| °C

PROGRAMMER INSTRUCTION:

- SOFT EDIT: DISPLAY SOFT EDIT IF TEMPERATURE IS ≥ 20.0 °C OR IF ≤ 0.0 °C.

BL3400/(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.

- IF THERE ARE NOT ANY TUBES THAT REQUIRE REFRIGERATED TRANSPORT TEMPERATURES, THEN SELECT “NO, NOT IN CHAMBER”.

YES, IN CHAMBER..... 1
 NO, NOT IN CHAMBER..... 2

BL3500/(COLD_THRESHOLD_HIGH). STATUS OF REFRIGERATED CHAMBER HIGH THRESHOLD MONITOR

DATA COLLECTOR INSTRUCTIONS:

- RECORD STATUS OF THE HIGH THRESHOLD MONITOR IN THE REFRIGERATED COMPARTMENT OF THE COOLER.
- IF THERE ARE NOT ANY TUBES THAT REQUIRE REFRIGERATED TRANSPORT TEMPERATURES, THEN SELECT “NO, NOT IN CHAMBER”.

YES, IN CHAMBER..... 1
 NO, NOT IN CHAMBER..... 2

BL3600/(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.
- IF THERE ARE NOT ANY TUBES THAT REQUIRE AMBIENT TRANSPORT TEMPERATURES, THEN SELECT “NO, NOT IN CHAMBER”.

YES, IN CHAMBER..... 1
 NO, NOT IN CHAMBER..... 2

BL3700/(BLOOD_DRAW_COM). BLOOD DRAW OTHER COMMENTS

DATA COLLECTOR INSTRUCTION:

- ENTER BLOOD COLLECTION COMMENTS:

NO COMMENTS..... 1 **(TIME_STAMP_5)**
 COMMENT..... 2

BL3750/(BLOOD_DRAW_COMMENT).

DATA COLLECTOR INSTRUCTION:

- ENTER ANY OTHER BLOOD COLLECTION COMMENTS.

PROGRAMMER INSTRUCTION:

LIMIT FREE TEXT TO 255 CHARACTERS.

(TIME_STAMP_5) PROGRAMMER INSTRUCTION:

INSERT DATE/TIME STAMP