



## Biospecimen Infant Blood Spot Instrument

<b>Event:</b>	Birth
<b>Participant:</b>	Child
<b>Respondent:</b>	Data Collector
<b>Domain:</b>	Biospecimen
<b>Type of Document:</b>	Data Collection Instrument
<b>Allowable Mode:</b>	In-Person (CAPI)
<b>Allowable Method:</b>	Interviewer-Administered
<b>Recruitment Groups:</b>	EH, PB, HI, PBS
<b>Version:</b>	1.0
<b>Release:</b>	MDES 3.3

Public reporting burden for this collection of information is estimated to average 2 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 Infant Blood Spot Instrument

## TABLE OF CONTENTS

GENERAL PROGRAMMER INSTRUCTIONS.....	1
BIOSPECIMEN BLOOD SPOT COLLECTION	3

# Biospecimen Infant Blood Spot 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	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	
UNIT AND PHONE FIELDS	10	
_OTH AND COMMENT FIELDS	255	
FIRST NAME AND LAST NAME	30	
ALL ID FIELDS	36	
ZIP CODE	5	
ZIP CODE LAST FOUR	4	
CITY	50	
DOB AND ALL OTHER DATE FIELDS (E.G., DT, DATE, ETC.)	10	<ul style="list-style-type: none"> <li>• DISPLAY AS MM/DD/YYYY</li> <li>• STORE AS YYYY-MM-DD</li> <li>• HARD EDITS: MM MUST EQUAL 00 TO 12 DD MUST EQUAL 01 TO 31 YYYY MUST BE BETWEEN 1900 AND CURRENT YEAR.</li> </ul>
TIME VARIABLES	TWO-DIGIT HOUR AND TWO-DIGIT MINUTE, AM/PM DESIGNATION	<ul style="list-style-type: none"> <li>• HARD EDITS: HOURS MUST BE BETWEEN 00 AND 12; MINUTES MUST BE BETWEEN 00 AND 59</li> </ul>

## 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 STUDY CENTERS 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 BLOOD SPOT COLLECTION

### (TIME\_STAMP\_IBS\_ST) PROGRAMMER INSTRUCTION:

- INSERT DATE/TIME STAMP

IBS010/(R\_FNAME)(R\_MNAME)(R\_LNAME). MOTHER'S NAME:

_____ FIRST NAME (M_FNAME)	_____ MIDDLE NAME (R_MNAME)	_____ LAST NAME (R_LNAME)
----------------------------------	-----------------------------------	---------------------------------

IBS020/(C\_FNAME)(C\_LNAME). CHILD'S NAME:

_____ FIRST NAME	_____ LAST NAME
---------------------	--------------------

IBS030/(CHILD\_DOB). CHILD'S DATE OF BIRTH:

### DATA COLLECTOR INSTRUCTION:

- ENTER A TWO-DIGIT MONTH, TWO-DIGIT DAY, AND A FOUR-DIGIT YEAR.

MONTH: |\_\_|\_\_|  
          M  M

DAY: |\_\_|\_\_|  
      D  D

YEAR: |\_\_|\_\_|\_\_|\_\_|  
       Y  Y  Y  Y

### PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
- HARD EDIT: INCLUDE HARD EDIT IF DATE IS GREATER THAN CURRENT DATE.

IBS040/(CHILD\_DOB\_TIME). TIME OF CHILD'S BIRTH:

### DATA COLLECTOR INSTRUCTIONS:

- RECORD THE TIME AS HH:MM.
- BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY.

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

### PROGRAMMER INSTRUCTIONS:

- HARD EDIT: INCLUDE HARD EDIT IF TIME IS GREATER THAN CURRENT TIME.

IBS050/(CHILD\_DOB\_TIME\_UNIT). TIME UNIT OF CHILD'S BIRTH – AM/PM:

**DATA COLLECTOR INSTRUCTIONS:**

- CHOOSE “AM” OR “PM” FOR CHILD’S TIME OF BIRTH.

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

**IBS060/(CHILD\_BLOOD\_TRANS).** HAS THE CHILD RECEIVED A BLOOD TRANSFUSION?

YES..... 1  
NO..... 2

**IBS070/(HEEL\_STICK\_DATE).** DATE HEEL STICK WAS PERFORMED:

**DATA COLLECTOR INSTRUCTION:**

- ENTER A TWO-DIGIT MONTH, TWO-DIGIT DAY, AND A FOUR-DIGIT YEAR.

MONTH: |\_\_|\_\_|  
          M  M  
DAY:   |\_\_|\_\_|  
          D  D  
YEAR:  |\_\_|\_\_|\_\_|\_\_|  
          Y  Y  Y  Y

**PROGRAMMER INSTRUCTIONS:**

- HARD EDIT: INCLUDE HARD EDIT IF YEAR IS < 2012.
- HARD EDIT: INCLUDE HARD EDIT IF DATE IS GREATER THAN CURRENT DATE.

**IBS080/(HEEL\_STICK\_TIME).** TIME HEEL STICK WAS PERFORMED:

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD THE TIME AS HH:MM.
- BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY.

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

**PROGRAMMER INSTRUCTIONS:**

- HARD EDIT: INCLUDE HARD EDIT IF TIME IS GREATER THAN CURRENT TIME.

**IBS090/(HEEL\_STICK\_TIME\_UNIT).** TIME UNIT HEEL STICK WAS PERFORMED – AM/PM:

**DATA COLLECTOR INSTRUCTIONS:**

- CHOOSE “AM” OR “PM” FOR TIME HEEL STICK WAS PERFORMED.

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

**IBS100/(BLOOD\_OBTAIN\_METHOD). HOW WAS THE BLOOD OBTAINED?**

FREE FLOWING..... 1  
MILKED..... 2

**IBS110/(NUM\_SPOTS\_PSC). NUMBER OF SPOTS FILLED ON PROTEIN SAVER CARD (0-4):**

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD A NUMBER BETWEEN 0 AND 4.
- BE SURE TO FILL THE SPACE WITH A ZERO WHEN NECESSARY.

NUMBER OF SPOTS FILLED

**PROGRAMMER INSTRUCTIONS:**

- HARD EDIT: INCLUDE HARD EDIT IF NUMBER IS > 4.

**IBS120/(NUM\_SPOTS\_FTA). NUMBER OF SPOTS FILLED ON FTA CARD (0-2):**

**DATA COLLECTOR INSTRUCTIONS:**

- RECORD A NUMBER BETWEEN 0 AND 2.
- FILL SPACE WITH A ZERO WHEN NECESSARY.

NUMBER OF SPOTS FILLED

**PROGRAMMER INSTRUCTIONS:**

- HARD EDIT: INCLUDE HARD EDIT IF NUMBER IS > 2.
- IF **NUM\_SPOTS\_PSC** < 4 OR IF **NUM\_SPOTS\_FTA** < 2, GO TO **6SPOT\_REASON**.
- OTHERWISE, GO TO **DATA\_COLLECTOR\_ID**.

**IBS130/(6SPOT\_REASON). IF FEWER THAN 6 TOTAL SPOTS WERE FILLED (BOTH CARDS COMPLETED), CHOOSE ONE REASON THAT BEST DESCRIBES WHY.**

PARTICIPANT REFUSAL..... 1  
PARENT/GUARDIAN REFUSAL..... 2  
QUANTITY NOT SUFFICIENT..... 3  
DEFECTIVE KIT..... 4  
OTHER.....-5

**PROGRAMMER INSTRUCTIONS:**

- IF **6SPOT\_REASON** = -5, GO TO **6SPOT\_REASON\_OTH**.
- OTHERWISE, GO TO **DATA\_COLLECTOR\_ID**.

**IBS140/(6SPOT\_REASON\_OTH).**

SPECIFY: \_\_\_\_\_



