



Infant Blood Spot Instrument

Event Category:	Time-Based
Event:	Birth
Administration:	N/A
Instrument Target:	Child
Instrument Respondent:	Data Collector
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:	3 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.

Public reporting burden for this collection of information is estimated to average 3 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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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	DATA TYPE	PROGRAMMER INSTRUCTIONS
ADDRESS AND EMAIL FIELDS	100	CHARACTER	
UNIT AND PHONE FIELDS	10	CHARACTER	
_OTH AND COMMENT FIELDS	255	CHARACTER	<ul style="list-style-type: none"> • Limit text to 255 characters
FIRST NAME AND LAST NAME	30	CHARACTER	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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.**

INFANT BLOOD SPOT INSTRUMENT

(TIME_STAMP_IBS_ST).

PROGRAMMER INSTRUCTIONS

- INSERT DATE/TIME STAMP
- PRELOAD PARTICIPANT ID (P_ID) FOR THE CHILD.

IBS01000. AS PART OF THE NATIONAL CHILDREN'S STUDY (NCS), WE ARE COLLECTING A BLOOD SAMPLE FROM AN INFANT HEEL STICK FOR PARTICIPANTS. UP TO FOUR (4) BLOOD SPOTS WILL BE COLLECTED ON A WHATMAN 903 PROTEIN SAVER CARD.

DATA COLLECTOR INSTRUCTIONS

- UP TO FOUR (4) BLOOD SPOTS WILL BE COLLECTED ON A WHATMAN 903 PROTEIN SAVER CARD FROM A ROUTINE HOSPITAL INFANT HEEL STICK PERFORMED BY HOSPITAL STAFF.
- A SECOND HEEL STICK TO OBTAIN A SPECIMEN FOR NCS COLLECTIONS SHOULD NOT BE PERFORMED.
- COMPLETE THIS INSTRUMENT WITH THE BEST INFORMATION AVAILABLE.

IBS04000/(CHILD_BLOOD_TRANS). HAS THE CHILD RECEIVED A BLOOD TRANSFUSION?

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

IBS05000/(NUM_SPOTS_PSC).

NUMBER OF SPOTS FILLED ON PROTEIN SAVER CARD (0-4):

|_|

NUMBER OF SPOTS FILLED

DATA COLLECTOR INSTRUCTIONS

- IF PROTEIN SAVER CARD NOT COLLECTED, RECORD 0 AS NUMBER OF SPOTS FILLED.

PROGRAMMER INSTRUCTIONS

- IF NUMBER OF SPOTS FILLED = 0, GO TO **FOUR_SPOT_REASON**.
- OTHERWISE, GO TO **SPECIMEN_ID**.

IBS06000/(SPECIMEN_ID).

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PROGRAMMER INSTRUCTIONS

- DISPLAY HARD EDIT IF SPECIMEN ID IS NOT FORMATTED AS TWO ALPHA,

PROGRAMMER INSTRUCTIONS

SEVEN NUMERIC CHARACTERS DASH TWO ALPHA, TWO NUMERIC CHARACTERS (AA#####-AA##);

IBS07000. DATE AND TIME HEEL STICK WAS PERFORMED

(HEEL_STICK_MM)

|_|_|
M M

Label	Code	Go To
DON'T KNOW	-2	

(HEEL_STICK_DD)

|_|_|
D D

Label	Code	Go To
DON'T KNOW	-2	

(HEEL_STICK_YYYY)

|_|_|_|
Y Y Y Y

Label	Code	Go To
DON'T KNOW	-2	

(HEEL_STICK_TIME)

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

Label	Code	Go To
DON'T KNOW	-2	

(HEEL_STICK_TIME_UNIT)

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

IBS08000/(BLOOD_OBTAIN_METHOD). HOW WAS THE BLOOD OBTAINED?

Label	Code	Go To
FREE FLOWING	1	
MILKED	2	
DON'T KNOW	-2	

PROGRAMMER INSTRUCTIONS

- IF NUM_SPOTS_PSC = 4, GO TO SPECIMEN_DC_COMMENTS.

PROGRAMMER INSTRUCTIONS

- IF NUM_SPOTS_PSC = 1 - 3, GO TO FOUR_SPOT_REASON.

IBS12000/(FOUR_SPOT_REASON). IF FEWER THAN 4 TOTAL SPOTS WERE FILLED, CHOOSE ONE REASON THAT BEST DESCRIBES WHY:

Label	Code	Go To
PARTICIPANT REFUSAL	1	SPECIMEN_DC_COMMENT S
PARENT/GUARDIAN REFUSAL	2	SPECIMEN_DC_COMMENT S
BLOOD FLOW NOT SUFFICIENT	3	SPECIMEN_DC_COMMENT S
OTHER	-5	

IBS13000/(FOUR_SPOT_REASON_OTH).

SPECIFY: _____

IBS14000/(SPECIMEN_DC_COMMENTS). DO YOU HAVE ANY COMMENTS ABOUT THE INFANT BLOOD SPOT COLLECTION THAT WERE NOT ALREADY NOTED?

Label	Code	Go To
YES	1	
NO	2	TIME_STAMP_IBS_ET

IBS15000/(SPECIMEN_DC_COMMENTS_OTH). INFANT BLOOD SPOT COLLECTION COMMENTS NOT ALREADY NOTED

SPECIFY: _____

(TIME_STAMP_IBS_ET).

PROGRAMMER INSTRUCTIONS

INSERT DATE/TIME STAMP